VOL. 30, NO. 6 JUNE 1975

Food Drug Cosmetic Law JOURNAL

Freedom of Information Act—Regulations of the Food and Drug Administration . . . Papers and Discussion

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $25; single copies, $3. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

June, 1975
Volume 30 • Number 6

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

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TO THE READER

The FDA's Freedom of Information Act Regulations. This month's issue of the *Journal* is devoted to the Freedom of Information Act Regulations issued by the Food and Drug Administration. The material presented resulted from a briefing session on the regulations, held by the Food and Drug Law Institute in Arlington, Virginia on March 12, 1975.

Daniel F. O'Keefe, Jr. introduces the subject with a summary of the regulations. Complete with paragraph references, the article details what information is available and how it can be obtained. As president of the Food and Drug Law Institute, Mr. O'Keefe served as moderator of the briefing session. His article, "The FDA's Freedom of Information Act Regulations," begins on page 312.

Robert C. Brandenburg, Director of the Compliance Regulation Policy Staff in the Office of the Associate Commissioner for Compliance in the Food and Drug Administration, discusses the FOI Act regulations from the FDA's viewpoint. Dealing with the past, the present and the future under the Act, he cites figures of requests received and granted. "Information Requests Under the FOI Act" begins on page 321.

"Problems and Opportunities Under the Public Information Regulations of the FDA" is an article by *William R. Pendergast* on page 326. Mr. Pendergast, a member of the law firm of McMurray and Pendergast, emphasizes the areas of product development, comparative advertising and acquisitions in his examination of the type of data at the FDA now available to the public.

Warren E. Whyte's article is a discussion of the regulations and their effect on drug companies. Mr. Whyte, Senior Attorney of Regulatory Affairs of Abbott Laboratories, is concerned about the complexity of these regulations and the possibility of confidential information being released to the public. Beginning on page 338, the article is titled "Drug Company Concerns and Opportunities—How We Will Cope."

In "Food Company Concerns and Opportunities—How We Will Cope," *Gary A. Sunshine* expresses concern that contact between the FDA and industry will diminish because of the regulations. Mr. Sunshine, whose article begins on page 345, is Director of the Regulatory Law Department of ICI United States, Inc.

As Vice-President of Legal Affairs of Revlon, Inc., *Jack L. Most* discusses the most troubling aspects of the regulations and offers a guideline of five suggestions to help the cosmetic industry cope. His article, "Cosmetic Company Concerns and Opportunities—How We Will Cope," begins on page 350.

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Food·Drug·Cosmetic Law
Journal

The FDA's Freedom of Information Act Regulations

By DANIEL F. O'KEEFE, JR.

Mr. O'Keefe Is President of the Food and Drug Law Institute.

THE FREEDOM OF INFORMATION (FOI) ACT became effective in 1967 as an amendment to the Administrative Procedure Act of 1946. The FOI Act was most recently amended in 1974. Senator Kennedy characterized the latest amendments as an "important reaffirmation of our national commitment to the principle that the American people should know how their government is being run."

One could raise interesting questions about the desirability of all this "openness." For example, Harlan Cleveland, former Ambassador to NATO and the Director of the Aspen Program in International Affairs, has said:

"The evidence is piling up that the very great benefits of openness and wide participation are being offset by the risks of making it difficult or impossible to get done the complicated things that have to be done if we are going to protect our surroundings, our bodies and ourselves."

However, Congress has set the basic policy, and our main focal point today is to address practical questions, such as what the Food and Drug Administration (FDA) will and will not release, whether the regulations properly interpret the law, and what the concerns of various groups are and how they are going to deal with the regulations.

Summary of the Regulations

A. *General Overview*

The task has fallen to me to summarize the regulations—regulations which I did not write and which some have said defy interpretation and explanation. Nevertheless, I will highlight them briefly —at the risk of some overgeneralization—and leave matters of interpretation and explanation to our friends from the FDA.

The regulations, like the Savior, arrived in final form on Christmas Eve, when a new babe of some 15 pages was born—preambled by 307 numbered paragraphs covering 40 pages, all swaddled in the *Federal Register*.

The new child, first proposed in May of 1972, was nurtured by almost 700 comment letters sent to its father— the FDA, or PBH, or both—and gestated for 2½ years in the womb in Rockville.

While its final coming has been recent, the preamble informs us that the regulations have been working miracles for over two years. And, indeed, the preamble provided 60 days for further comment on new matters and promised consideration of such comments and possible changes yet to come. So, while the regulations are now final, they are not quite final. But they are probably final enough. That is, unless you want to accept the cordial invitation of the Commissioner to "institute legal action in the courts to contest their validity" and, if successful, have them declared an abortion.

B. *General Policy*

The general policy of the Agency is well illustrated by the Commissioner's statement in the preamble (¶ 2) that the regulations generally place no burden on the public to justify a request for information. The burden for nondisclosure is placed on companies which have submitted information. In short, he states that "under the law, any person is entitled to receive information unless it is subject to one of the stated exemptions." (See also Section 4.20.)

The impact of this policy is demonstrated by the comment that ninety percent of the records in the FDA's files are now publicly available. Prior to May of 1972, only ten percent were available. (¶ 1.) The Commissioner asserts that the new policy has benefited the Agency and that it has not hindered communications or relations with those outside of government these past two years. (¶ 1.)

He pledges to make even greater use in the future of his discretionary authority to release records. (¶ 1.) The Commissioner reserves the right in Section 4.82 to release—with certain specific exceptions relating generally to trade secrets, personnel and medical files—all or part of any FDA record when he determines that it is in the public interest to do so.

General Theme

A general theme running throughout the preamble is that the Commissioner has decided to disclose or not disclose records based on his view of the statutory mandate. For example, in rejecting a comment that the open disclosure policy would increase product liability litigation, the Commissioner finds that is not a factor to be considered under the FOI. (¶ 4.) Similarly, he states that he has no discretion to release trade secret information under the law. (¶ 126.)

Therefore, generally, all FDA records, regardless of when received (¶ 36), are available to the public on request and without justification of need. The records are available except where confidence is required to protect: (1) individual (not corporate) rights to privacy; (2) trade secrets and confidential commercial or financial information; and (3) the need for the Agency to promote frank internal policy deliberations and to function effectively. (Section 4.20.)

C. *How to Obtain Records*

Anyone may obtain records by sending a written request to the public records and documents center of the FDA describing what he wants. (Section 4.40.) Within ten days of receipt of a request, the FDA is to write the requester explaining the extent to which the Agency will comply and stating reasons for any denial of records. (Section 4.41.) Fees for searching and copying are authorized. (Section 4.42.) In some cases, fees may be waived. Information requested will be furnished "as soon as possible." (¶ 47.) Denials of requests for information are signed by the Assistant Commissioner for Public Affairs (Section 4.47), and appeal lies to the Assistant Secretary for Health in the Department of Health, Education and Welfare (HEW). (Section 4.41(b)(4).) (See also ¶ 45-57, 67-73.)

Court review is available to those denied information by the Agency and the burden, in a *de novo* court proceeding, is on the Agency to sustain its actions.

Judicial review to prevent a proposed disclosure by the FDA is available in two ways. First, a declaratory judgment action challenging the regulations themselves may be filed. (¶ 307.) Second, if you learn of a proposed disclosure of specific records and have unsuccessfully sought FDA confidential treatment of them, the regulations provide five days to institute suit to enjoin their release. (Section 4.46, ¶ 65.)

D. *Government Records*

Obviously, there are two basic sources of information in the FDA's files. The first is internal—within government—records, discussions, memoranda, studies, reports, etc. which are the work product of the FDA or are between the FDA and another government agency. The second source is information submitted to the FDA by companies or others outside of government. I will discuss internal government information first.

Three exemptions to the FOI Act are particularly relevant: (1) the exemption for interagency or intra-agency memoranda; (2) the exemption to protect individual privacy; and (3) the limited exemption for investigatory records.

Generally, FDA records relating to "administrative enforcement action" are publicly available. These records include correspondence with companies following factory inspection, recall or detention requests, regulatory and information letters, and forms FD 483 and 2275 furnished to companies after factory inspection. (Section 4.101, ¶ 151-165, ¶ 110-113.) Investigatory records compiled for law enforcement purposes generally are releasable after consideration of enforcement action is closed; that is, after a decision has been made not to take action or action has been taken. If court action is involved, release is possible after that has been concluded by the running of the statute of limitations, exhaustion of appeals, or a final decision has been reached by the Agency or the United States Attorney not to proceed. (Section 4.64, ¶ 110-113.) Such records are released, except if disclosure would reveal a confidential source or investigative techniques. (Section 4.64.) Records relating to Section 305 hearings are generally treated in this manner. Names of individuals considered for possible criminal prosecution, but who were not prosecuted, generally are not released. (Section 1.6, ¶ 15 *et seq.*) However, corporate names are released. (¶ 15.)

Results of all research or testing conducted by the FDA or with its funds are publicly available when the final report is accepted by the Agency, as is access to raw data and other working material. (Section 4.105.) Also, consumer and compliance surveys are available, as are compliance programs and work plans of the bureaus and field offices after deletion of firm names, location of specific activities and other similar information. Even this information is available after a program is completed. (Section 4.106.) Legislative comments and proposals are not available until after submission, nor are records relating to internal planning and budgeting. (Section 4.106.) FDA staff manuals which affect the public are available, as are action levels which are used to determine whether the Agency will take regulatory action. (Section 4.107.) (See also ¶ 189-194.)

Written agreements between the FDA and other government agencies generally are available (Section 4.108, ¶ 195-197), as is correspondence and summaries of oral discussions between FDA officials and others, with the exception of members of the executive branch of the federal government. (Section 4.103-4.104, ¶ 166-178.)

Identity of Informant

Normally, names of individual FDA employees noted on disclosable records are not deleted, except in order to protect the identity of an informant or to protect the physical safety of an employee. (Section 4.32, ¶ 21.)

The availability of internal memoranda and other documents supporting regulations of the Agency is to be dealt with in the new procedural regulations still under consideration. (¶ 14.)

However, the FOI regulations provide that written memoranda within the executive branch may be withheld except to the extent factual information may be segregated and released. (Section 4.62.) Thus, underlying data and information ordinarily will be released. However, FDA analysis, including deliberative and policy discussion, and staff recommendations apparently will not be released. (¶ 100-102.)

E. *Information Submitted by Companies*

Turning to information which is or has been submitted to the Agency by companies or others outside of government, we find that correspondence with the Agency is publicly available (Section 4.103),

as are summaries of oral discussions (Section 4.104). If more than one summary is available, both will be released. (Section 4.104.) (See also ¶ 166-178.)

The FDA will release information already in its files and received from outside sources without giving notice of a request to the source. This assumes the information is not protected by one of the exemptions in the FOI Act or regulations.

In cases of uncertainty, that is, where the FDA is uncertain whether requested information should be released as "confidential," the FDA will consult the person submitting it. Where no question exists in the FDA, however, the information will be released—without notice. (Section 4.45, ¶ 62-64.)

Information Voluntarily Submitted

There is a procedure to obtain a decision on a request of confidentiality for information *voluntarily* submitted in the future. Section 4.44 provides that the information and the request may be sent to the director of the bureau involved or to the Associate Commissioner for Compliance. Such a request should state why the information should be confidential under the regulations. If the request is upheld, the FDA will not release the data, except under court order. If the request is denied, the submitter may withdraw the information. (Section 4.44.) Marking data as "confidential," and oral assurances by the FDA, have no effect. (Section 4.27, ¶ 58.) (See also ¶ 38-39.)

Information submitted to the FDA by those outside of government normally is releasable—whether submitted voluntarily or pursuant to legal requirement—unless its release is exempted by the FOI Act. The principal relevant exemptions are for trade secrets and confidential commercial or financial information.

F. *Trade Secrets*

The portion of the proposed regulation which evoked the most extensive comments related to these exemptions and their application. Information which is a "trade secret" or "confidential commercial or financial information" cannot legally be released. The Commissioner has no discretion, as he has with other information. (¶ 78.) The big questions, however, are to determine what constitutes a "trade secret" and what is "confidential commercial or financial information."

The FDA has defined a "trade secret" basically as it is defined in the Restatement of Torts; namely, that a trade secret "may consist of any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." (Section 4.61, ¶ 78 *et seq.*)

Confidential commercial or financial information is defined in the regulations as "valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs." (Section 4.61.)

The fact that a particular manufacturer holds certain commercial information as confidential is not determinative since the test the FDA applies is whether it is customary to do so. (¶ 89.)

Industry Practice

Determination of trade secret status for information depends entirely on the competitive advantage attributable to the specific information involved—there is no specific competitive advantage involved if the information is generally held in confidence according to usual industry practice. (¶ 89.)

Trade secret protection, under the FDA regulations, is lost if the information is not *currently* providing a competitive advantage, unless a manufacturer can show in a specific factual setting that the data will provide a future competitive advantage. (¶ 86.) The FDA also says that "competitive advantage" is often significant in determining whether commercial information is privileged. (¶ 87.)

Any lawful public release of the information to anyone outside the company or its consultants (¶ 116 *et seq.*) destroys its privileged status. (¶ 89.)

Thus, under the regulations, when a request for information is made, the FDA will make a determination as to whether the information is privileged. If, in the FDA's judgment, it is not, the information will be released without notice. In cases of uncertainty, the FDA will consult the person providing the information. The FDA, however, will make the decision, subject to court action. If the Agency honors the confidentiality and suit is filed to order its release, the owner of the information is expected to defend the suit. If he does not, he is

deemed to have waived the confidentiality, and the information will be released. (Section 4.53, ¶ 73.)

G. *Specific Records*

Having touched on the broad parameters of the regulations, and the procedures under which they are to be implemented, I will now cover some of the important substantive data involving food, drugs, devices and cosmetics which will be affected by regulations.

Generally, in the case of foods, drugs, cosmetics and devices, the FDA will release at some point in time:

(1) safety, effectiveness and functionality information on products and ingredients;

(2) test protocols (unless privileged under the regulations);

(3) information relating to adverse reactions, product experience and consumer complaints (after deletion of names of users and third parties);

(4) lists of ingredients; and

(5) assay or other analytical methods (unless privileged under the regulations).

Generally, the FDA will not release manufacturing processes, quality control procedures, quantitative formulas, and production, sales and distribution information.

Safety, effectiveness and functionality data are defined to encompass all data from animal and human safety tests. It includes all studies conducted to establish basic identity, stability, purity, potency, bioavailability, performance and usefulness.

These rules apply—with some exceptions—with respect to information submitted voluntarily to the Agency. In such cases, safety, effectiveness and functionality information will be released for a marketed product or ingredient, but not for a developmental one unless the information previously has been publicly disclosed. (Section 4.111.)

The general rules apply to information in color additive petitions (Section 8.9) and food additive petitions (Section 121.51). The information is releasable after notice of the filing of the petition is published in the *Federal Register* or after the petitioner is notified it will

not be filed because of deficiencies. Correspondence and written summaries of oral discussions regarding the petitions are also available.

The general rules also apply with respect to information in antibiotic human drug files (Section 431.71) after an "approval" letter has been sent, and to a biological product file after a product license has been issued (Section 601.51). FDA and manufacturer testing records are also disclosed, as are correspondence and summaries of oral discussions.

Summaries

The general rules apply to information in Investigational New Drugs (IND) (Section 312.5), New Drug Application (NDA) (Section 314.14) and New Animal Drug Application (NADA) (Section 135.133a) files and in antibiotic veterinary drug files (Section 146.16). However, in these cases *all* safety and effectiveness information is *not* released unless previously publicly disclosed. Rather, summaries of safety and effectiveness data will be released instead. However, all safety and effectiveness information will be released if a NDA or NADA is finally abandoned, if a final determination is made that the application is not approvable, if approval has been withdrawn, or if a drug is determined not to be a new drug. Correspondence and summaries of oral discussions are also available as before.

Information in NADA files and antibiotic veterinary drug files is made available after approval is published in the *Federal Register*. (Section 135.33a, 146.16.) NDA file information is available after an "approvable" letter is sent to the applicant.

The existence of such files as IND, NDA and NADA will not be disclosed until the file material is releasable as previously described, unless publicly disclosed or acknowledged.

That concludes my brief summary. It would have taken more space to do justice to the task but I do hope that this summary has introduced you to the subject. **[The End]**

Information Requests Under the FOI Act

By ROBERT C. BRANDENBURG

Mr. Brandenburg Is Director of the Compliance Regulation Policy Staff in the Office of the Associate Commissioner for Compliance in the Food and Drug Administration.

AS ONE WHO FOR MANY YEARS has variously withheld and supplied Food and Drug Administration (FDA) file information from and to the public, I have been volunteered to discuss the topics of "How We Got Here," "Where We Are," and "Where We Go From Here and How We Get There" with respect to the FDA Public Information Regulations.

How *did* we get here? Many probably recall clearly the era prior to the Freedom of Information (FOI) Act when the avenue to the FDA files and personnel was mainly a "4.1 request." Then, with a private civil case in hand, pursuant to 21 CFR section 4.1, you would submit a duly notarized brilliant and articulate precis to the FDA telling why certain Agency files or the testimony of government employees were indispensable to your case. Almost invariably your response, particularly to a request for witnesses, was a brief courteous reply denying your request on the grounds that it was "contrary to the public interest."

Aside from such requests from attorneys, however, it was a rare day for others to seek information from the FDA files, except for congressional committees. Even with these, there was a prolonged and painful interplay before a set of informal ground rules were developed for their review of files which contained trade secrets. Strangely enough, what the FDA would supply to a committee under those ground rules a decade ago is almost identical to what it would supply to that same committee—or to any member of the public—under our new FOI regulations.

So for years the FDA functioned merely as a prosaic law enforcement agency with little file information being made public, and with little being requested.

Interesting Legal Curiosity

This was the status in 1967 when the FOI Act became effective. Along with most other agencies, I am afraid that the FDA looked at the new act as an interesting legal curiosity, nothing to bother about. The attitude of most for the next three or four years continued to be "ho-hum" or "so what?" Some agencies were being sued, including the FDA, but requests for information under the new act were few and far between. Basically, however, there was the growing albeit grudging recognition that FOI was here to stay and that scarce money and manpower would need to be devoted to it.

Following passage of the FOI Act, the Attorney General issued an interpretive memorandum in June 1967. The Department of Health, Education and Welfare (HEW) issued regulations in stages—June 30, 1967, October 27, 1967 and December 4, 1968. The FDA FOI observance, such as it was, was guided by these.

By late 1971 it became obvious to the FDA that, because the types of documents in its files differed markedly from those in the files of other HEW agencies, specific FDA regulations needed to be formulated. After much grunting and groaning, this was done and they were published as a proposal on May 5, 1972. In response, the FDA received 667 letters, 68 of which made substantive comments. In the meantime, the FDA had been sued by Carolyn Morgan who had sought certain files under FOI which were considered by the Agency to be exempt from disclosure. In June 1971, the FDA was granted summary judgment by the District Court and this was promptly appealed. So although the FDA's painstaking evaluation of the comments received was completed by the fall of 1972, the decision was made not to issue final regulations until the conclusion of the *Morgan* case. In the interim, the proposed regulations were implemented. A decision was made in the *Morgan* case on May 24, 1974[1] which did not adversely affect the Agency stance. With the conclusion of other pressing business, the drafting of the final regulations was begun. During this process some FOI amendments were "ping-

[1] *Carolyn D. M. Morgan v. FDA et al.*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 41,147, Civil Action 1978-70, No. 71-1709 (DC D of C, May 24, 1974).

ponged" between the Congress and the President. Finally enacted, they caused almost no change in the document already drafted except for minor changes in the preamble. These final regulations were published in the *Federal Register* on December 24, 1974 and became effective on January 23, 1975.

That's how we got here.

Agency Thinking

So, where are we? The most important attainment has been an attitudinal switch in Agency thinking. The FOI Act provisions are no longer viewed as providing means for outsiders to intrude in FDA affairs. Rather, they embraced positively as expressions of Agency intent and policy.

Along with the change in attitude has come new support for the function of making responses to requests as quickly as possible. Those familiar with the FDA paperwork burden, however, know that this is a gargantuan task and the resources of the Agency are hard at work at it. A management survey team has reviewed and revamped the entire operation in light of the provisions of the final regulations and has drawn up and issued implementing guidelines. A paperwork management study has been conducted and appropriate changes have been made in routing, handling, recording and filing. A national training seminar, attended by FDA FOI officers from all field and headquarters units, has been held primarily to familiarize all with the new procedures for uniformity of handling and, secondarily, to impress all with the Agency policy and intent. We do not claim perfection at this point in time. We still have rough edges but they will soon be rounded off in the crucible of experience. The ultimate aim is to have the most efficient and responsive FOI operation in government.

Facts and Figures

At this point, some current facts and figures will be interesting and informative. For convenience we have chosen the 18 months comprising fiscal year 1974 and the first half of fiscal year 1975. During this period we received a total of 3179 FOI requests, of which 3121 or 98.2% were granted and 58 or 1.8% were denied. We should add, however, that in many cases of the denials, some documents requested were granted. And what was requested? Perhaps not too surprising, the FDA manuals and compliance policy guides are high on the "best

seller" list with 607 requests. These are exceeded only by Establishment Inspection Reports and Sample Analyses—657 requests. Third are requests for advisory committee minutes—426. The remainder, ranging from 382 to 57, are (in order): miscellaneous reports; information on specific drugs; consumer complaint records; adverse drug reactions; recall information; drug labeling; biological regulations; and licensing.

Of the requests denied in whole or in part, attorneys lead the list with 42%. Those who identify themselves as industry representatives, usually as officers of particular firms, are next with 35%. Individuals lag behind with 9%; those who identify themselves as consumer advocates with 9%; and the remaining 5% of the refusals are to those we are unable to categorize.

Reasons for Denials

What are the reasons for these denials? In over half the cases the request was for information, usually an establishment inspection report, from an open investigatory file. The FDA is basically a regulatory agency. In about 20% of the cases, trade secrets were refused. Next (15%) were requests for personnel files, medical files and other disclosures of personal information, and requests for interagency and intra-agency memos (8%).

Of these 58 requests denied (or 1.8% of all requests), the requesters have appealed the denial to HEW in seven instances. The Department has reversed the denial twice in the period. All in all, we think we have an excellent track record.

In considering time frames, however, we must be less than self-congratulatory. Only about a third of all requests were answered within two weeks and approximately 12% took longer than 60 days. When only refusals are considered, performance was even less satisfactory since the time between the initial request and the sending of a denial letter averaged well over three months. It was for this reason that the entire procedure had to be reconsidered and revamped.

5,000 Pieces of Mail

As a postscript, however, it must be observed that FOI requests come to the Agency as part of the 5,000 pieces of mail handled daily, that many need to be read carefully to determine that they are, in fact, FOI requests, and that the time frames referred to started when

the request arrived at FDA, not when it arrived at the FDA unit responsible for handling it. The new procedures should insure that properly flagged FOI requests will reach the responding unit with no delay and that others will be handled very expeditiously upon recognition of the true nature of the request.

And where do we go from here? How do we get there?

Hopefully, the FDA's FOI regulations are not engraved in seashore sand to be changed by the vagaries of each tide but, equally important, they are not engraved in any substance impervious to changes called for by experience and common sense.

Offer Comments

Further, we have asked reviewers to offer comments on these regulations. Also, in the preamble, the Commissioner has invited those who disagree with these final regulations, and whose additional comments have not been persuasive to him, to test their validity in the courts.

Finally, in addition to any changes made because of experience or by court order there may well be changes occasioned by new legislation. For example, the new Privacy Act of 1974 or another act dealing with personal privacy now in final drafting will likely have an impact on these regulations, although not major.

New Logistics

Basically, under the amended FOI Act and our new regulations we expect release statistics to continue about the same—over 98% of the requests to be granted, less than 2% to be denied. Conversely, with our new logistics, we have decreased handling time of new requests to that called for in the statute and are expediting the handling of those old requests which were already in the pipeline.

As an epilogue addressed to those attorneys who still remember the 4.1 days: If you have a private civil suit and make a request for testimony of FDA witnesses under the provisions of our new regulations, you will still probably receive a polite refusal. [The End]

Problems and Opportunities Under the Public Information Regulations of the FDA

By WILLIAM R. PENDERGAST

Mr. Pendergast Is a Member of the Law Firm of McMurray and Pendergast.

THE FREEDOM OF INFORMATION ACT was passed in order to insure an informed electorate by providing the fullest possible public access to documents on file within the federal government.[1] This was the goal, but this is not what happened, and what did happen apparently comes as a surprise to many. As one commentator puts it, in describing seven years of experience with the Freedom of Information (FOI) Act:

"The benefits of the [FOI] Act have inured predominantly to private, not public, interest. It is the corporation seeking through disclosure an economic, competitive or legal advantage, not the common citizen seeking civic enlightenment, that has most often challenged wrongful agency withholding of public information."[2]

And so it is. In this paper we shall analyze the FOI regulations of one agency—the FDA—to determine what opportunities there are for companies regulated by that Agency as well as to determine how those same companies can safely operate under these regulations.[3] A

[1] H. Rept. 1497, to accompany S. 1160, 89th Cong., 2d Sess.; 2 U. S. C., Congressional and Administrative News, 2418, 2429 (89th Cong., 2d. Sess., 1966). This legislation was under consideration for ten years and the debates are replete with instances where the public was denied access to information in government files. See "Comments on Proposed Amendments to Sec. 3 of the Administrative Procedure Act: The Freedom of Information Bill," 40 *Notre Dame L. Rev.* 417 (1965).

[2] "The Freedom of Information Act: A Seven Year Assessment," 74 *Col. L. Rev.* 895, 958 (1974).

[3] The regulations appear at 39 *F. R.* 44642 (Dec. 24, 1974). There is an extensive preamble (307 numbered paragraphs) that precedes the regulations. 39 *F. R.* 44602. This preamble consti-

(Continued on the following page.)

discussion of how it came about that industry is more interested in FOI problems than others must await another time.[4]

There are two aspects to these regulations. First of all, how does a corporation which has done and is doing business with the FDA protect the confidentiality of its contacts with that Agency? Secondly, what are the opportunities available as a result of these regulations? In order to provide a clearer presentation, it is better to begin with the opportunities.

Opportunities

The opportunities can be divided into two parts:

(1) those documents that provide useful information about how the FDA operates, what it is up to, as well as the necessary documentation to insure that the FDA operates within its statutory authority;

(2) those FDA records containing useful information about competitive products and operations.

To begin with, the basic tools for understanding how the FDA operates, and the guidelines it follows, are the various manuals prepared by the Agency staff for its inspectors and scientists. These are all available, from the FDA, at a nominal cost.[5] These manuals cover such diverse topics as the operation instructions and programs for inspectors in the field, the FDA's bacteriological assay methods, general administrative guidelines, drug analysis methods and the food additive manuals.[6] Obviously, these texts provide a wealth of detail about how the FDA works. For instance, if one has certain tests to perform on food or drug products, he can check to see if he is using the same methods that the FDA finds appropriate; if he is new to dealing with FDA inspectors he can find out how the Agency expects them to behave (and thus he can insist that they behave that

(Footnote 3 continued.)
tutes an invaluable gloss on the regulatory text and should be preserved. It is unfortunate that, until now, these "preambles" have not been codified in the Code of Federal Regulations.

Unless otherwise noted all subsequent citations are to the December 24, 1974 *Federal Register*.

[4] It should be sufficient to point out that there are three groups which benefit from the FOI Act: the press which was largely responsible for its passage; the public; and corporate interests. The press, probably because of the ephemeral nature of the news, has not led the fight in obtaining documents under FOI law, while the public, doubtless because of the diffuse nature of that group, has been unable to. Only the last group—the corporate interests (and the Agency)—have had to face the problems of this law, and so come to benefit from it.

[5] Reg. 4.107, 39 *F. R.* 44650-1.

[6] See ¶ 193, 39 *F. R.* 44627 for a more complete list.

way); and, finally, he can keep up to date on the inspections programs the FDA is conducting; in other words he can know what the FDA is up to and how it goes about its work.

A thorough knowledge of the manuals can also be helpful should any legal battles develop between his company and the FDA. As an example, if he knows that an FDA inspector has failed to follow manual procedures in collecting a sample, he is in a position to argue that, because of this failure, any results obtained by an analysis of that sample may not be applicable to an entire lot of that product and therefore inconclusive on a charge of adulteration.[7]

Basic Documents

These manuals are the basic documents one should have to understand the FDA, but there are others available under the Public Information Regulations that are useful. One can get, for instance, the "action levels" and "tolerances on tolerances" that the FDA has developed over the years to decide whether to bring legal actions against products and their ingredients.[8] By comparing these figures with test results, it is possible to predict the likelihood of FDA regulatory action. In addition, all surveys, summaries of industry trends, and compilations of industry-wide data that the FDA develops from outside sources are available,[9] as are any data obtained by the FDA by contract with an outside source.[10] One can get a list of every New Drug Application (NDA) or New Animal Drug Application (NADA) granted since 1938 with the trade name of the product, the company involved, and, if such be the case, the date it came off the market.[11] Finally, it is possible to obtain all the analyses and testing, or research, conducted by the FDA whether in the FDA or by contract.[12] But, unlike the other data mentioned earlier, there are certain events that must occur before this happens.

According to the regulations, the results of all testing or research are available only when a *final* report is *complete* and it has been *accepted* by a responsible FDA official, and then only after deletion of

[7] In order for an analysis of a sample of a product to be applicable to the product as a whole, the sample must be "representative" of the whole. *United States v. 5 Cases . . . Figlia Mia*, 179 F. 2d 519 (CA-2 1950), cert. den. 339 U. S. 963; *United States v. 129 Cases . . . Ocean Perch*, 196 F. Supp. 255 (DC Me. 1961).

[8] ¶ 163, 39 *F. R.* 44623.

[9] Reg. 4.106, 39 *F. R.* 44650; ¶ 189-192, 39 *F. R.* 44626-7.

[10] Reg. 4.109, 39 *F. R.* 44651; ¶ 196-197, 39 *F. R.* 22627.

[11] Reg. 4.117, 39 *F. R.* 44652; ¶ 222-223, 39 *F. R.* 44630-1.

[12] Reg. 4.105, 39 *F. R.* 44650; ¶ 179-188, 39 *F. R.* 44625-6.

any confidential investigative techniques or procedures.[13] The possibilities for abuse, by allowing the FDA to continue to withhold information, are obvious. The Agency claims, however, that this regulation will not be used to avoid public disclosure of embarrassing data and that the mechanism is needed in order to avoid the premature release of tentative data or of as yet uncompleted reports.[14] Moreover, even this preliminary data will be released if it has previously been disclosed by an FDA employee in a speech, in correspondence, or in private conversations with outsiders.[15]

Leak to Trade Press

This last provision is a good point at which to discuss a related matter. *Any* record in FDA files is obtainable if it has been disclosed to the public by anyone, inside the FDA or out, but the disclosure must have been "authorized" or "lawful."[16] Thus, a leak to the trade press is an unauthorized disclosure and does not trigger public release, while a statement by a congressman is authorized and does trigger the entire disclosure mechanism.[17] Therefore, whenever an FDA official or employee speaks, whatever data he discusses is potentially available. This leads logically to the second aspect of obtaining documents from the FDA—the competitive opportunities of the Public Information Regulations.

The opportunities for obtaining information about competitors and competitive products are limited only by man's imagination. However, the greatest opportunities are available to companies involved in the manufacturing or distribution of either animal or human drugs. This may be so because drug manufacturers are required to submit many

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[13] Reg. 4.105(c), 39 *F. R.* 44650. The raw data, including slides and worksheets will also be available at this time. ¶ 182, 39 *F. R.* 44626.

[14] ¶ 181, 39 *F. R.* 44626. The Agency also contends that these tentative reports constitute intra-agency memorandums which are not required, by the FOI Act, to be disclosed.

[15] ¶ 184, 39 *F. R.* 44626.

[16] Reg. 4.21, 39 *F. R.* 44644; ¶ 29-31, 39 *F. R.* 44605.

[17] ¶ 30, 39 *F. R.* 44605; ¶ 89, 39 *F. R.* 44614; Reg. 4.81(a), 39 *F. R.* 44648. Disclosure to a consultant or to someone under a contractual obligation does not trigger the mechanism. However, the FDA recently departed from this mechanism so that when there was an unauthorized disclosure of certain proposed good manufacturing regulations, the Agency went ahead and made them available for public view. See "Large Volume Parenterals," 40 *F. R.* 6811 (Feb. 14, 1975).

reports that are not required, as yet, of food or cosmetic companies.[18] It is not possible to discuss all the areas of inquiry available under the FDA Public Information Regulations. Therefore, this paper will be confined to three: (1) product development; (2) comparative advertising; and (3) acquisitions.

Product Development

There are several ways in which the Public Information Regulations can help in bringing new products to the market. It will now be possible, for instance, to obtain a great deal of data about particular ingredients or chemical substances, including the safety, effectiveness and functionality data contained in food and color additive petitions and antibiotic drug forms.[19] This information is not made available right away; it is available only when there has been a notice of filing a petition in the *Federal Register* or of approval for a human antibiotic or biologic. For other human or animal drugs, similar information can be obtained, in a different and more complex manner.

To begin with, it is possible to determine what Investigational New Drugs (INDs) have been filed on a particular chemical only after the IND has been terminated,[20] and the FDA makes a very strict interpretation as to when such termination occurs. An IND is terminated or abandoned only after all human and animal work has been discontinued and, even then, only after the project is no longer under active development by its sponsor. It is not possible to obtain the data in INDs that are still active. However, if the sponsor or someone else has made a public disclosure about an IND, that fact can be verified through the FDA, and, in exceptional circumstances, the FDA may disclose more.[21] The data in master files are also obtainable, depending on the type of petition the data is used to support. Thus, if a particular master file has been used to support a food additive petition, data from it can be obtained, but if it has been used to support a pending IND, nothing in it will be disclosed.[22]

[18] The extensive reporting requirements imposed upon the drug industry appear at several places. For example: 21 U. S. C. 355(j); 21 U. S. C. 356(g) and the many regulations thereunder; 21 C. F. R. 310.300-304. We say "yet" with reference to food and cosmetic manufacturers because pending legislation could change all this. S. 641, 94th Cong., 1st Sess.

[19] Preamble, ¶ 230-237, 39 *F. R.* 44631-3; Reg. 8.9, 39 *F. R.* 44652 (color additives); Reg. 121.51(h), 39 *F. R.* 44653 (food additives); 431.71(e) (human antibiotic petitions); Reg. 501.5(e), 39 *F. R.* 44656 (biologics).

[20] ¶ 246, 39 *F. R.* 44633.

[21] Reg. 314.14(d), 39 *F. R.* 44654; 135.33a(d), 39 *F. R.* 44653.

[22] ¶ 226, 39 *F. R.* 44631.

Safety and Effectiveness Data

Furthermore, once a competitor brings an animal or human drug to the market with appropriate approval of a NDA or NADA, it becomes possible to obtain a summary of the safety and effectiveness data submitted in connection with that application.[23] These summaries describe the safety and effectiveness data that were submitted with or incorporated by reference in a particular application, and they are obtainable for any application approved to date. For applications approved on or after July 1, 1975, the summaries will be prepared by either the applicants themselves or by the FDA. Deleted from all summaries will be any information that would identify test subjects. In addition, for summaries for applications approved before July 1, 1975, any inappropriate or gratuitous comments made by the FDA will be removed.

These summaries will not satisfy the statutory requirement for the submission of "full reports" of the safety and efficacy data necessary to obtain FDA approval.[24] Thus, the submission of these summaries will not be sufficient to obtain an approved NDA, but that they prove invaluable is beyond dispute. They should tell anyone interested in the product how the products were tested, what questions were raised by the FDA, how they were resolved, including such perennial problems as bioavailability and assay procedures. Prudent use of these summaries should save a great deal of time in developing a product.

Adverse Reaction Reports

There are other items of information available from FDA files that may help to determine what products to study and bring to the market. For instance, adverse reaction reports for products can be obtained, with varying degrees of precision, depending upon the type of product involved. If it is a NDA or NADA drug, one can obtain all the adverse reaction reports, product experience reports and consumer complaints in FDA files.[25] If it is a food or a cosmetic,

[23] Reg. 314.14(e)(2), 39 *F. R.* 44654; Preamble, ¶ 238-252, 39 *F. R.* 44633-5 (for human drugs); Reg. 135.33a(e)(2), 39 *F. R.* 44653 (for animal drugs).

[24] For example: ¶ 259, 39 *F. R.* 44636, 21 U. S. C. 355(b)(1).

[25] Reg. 314.14(e)(4), 39 *F. R.* 44655 (human drugs); Reg. 135.33a(e)(4), 39 *F. R.* 44653 (animal drugs); Reg. 431.71(e)(3) (human antibiotics); Reg. 601.51(e)(3), 39 *F. R.* 44656 (biologics). In all cases the names of the persons suffering the reaction will be deleted as will any names of third parties. If a request is filed for information about a record pertaining to a specific individual, it will be denied unless the consent of that person is first obtained. Reg. 4.112(b), 39 *F. R.* 44652; ¶ 214, 39 *F. R.* 44629.

the extent of the adverse reactions obtainable depends upon who reported it to the FDA. If the adverse reaction was reported by the manufacturer of the cosmetic, the information will be given but only after deletion of any information which would identify the person who had used the product, the company, the name of the product or any third party such as the physicians who may have been involved. If, however, the adverse reactions were reported by a consumer or physician, their names will be deleted, but the name of the product or the company will not.[26] This sort of information obviously would be helpful in determining whether to market, or to continue to market, a particular product. Finally, protocols for testing products are also obtainable unless the owner of the protocol can establish that it is a trade secret.[27]

Comparative Advertising

A related area where the FDA files may contain useful documents is comparative advertising. If, for instance, one wishes to compare his product's blood levels with a competitor's, he can determine the levels by obtaining the appropriate data from the FDA. Similarly, if there are claims to be made about adverse reactions, such data, as we have seen, will be on file at the FDA in many cases and obtainable in most instances. In other words, whereas before it was sometimes difficult—if not impossible—to verify the reliability of a comparative claim, this verification should now be more easily accomplished.

Acquisitions

A third area where FDA files may be helpful is in acquisitions. If a company is interested in acquiring, or merging with, another company or if it wishes to purchase a product, it should now be possible to obtain better information about those companies or products. It may be useful to know, for instance, the nature of any legal difficulties the company has had with the FDA. One can now obtain any closed Section 305 hearing files.[28] Section 305 hearings are held under that Section of the Federal Food, Drug and Cosmetic Act to advise companies that the FDA is considering possible criminal action because of certain violations of the law.[29] A request for such files would disclose if the company has been in that sort of

[26] Reg. 4.111, 39 *F. R.* 44651; ¶ 200-213, 39 *F. R.* 44628-9. The FDA notes elsewhere that corporations have no constitutional right to privacy. ¶ 15, 39 *F. R.* 44603.

[27] See Reg. cited at footnote 25 and ¶ 279-81, 39 *F. R.* 44639.

[28] Reg. 1.6(e), 39 *F. R.* 44652-3; ¶ 15-25, 39 *F. R.* 44603-5. Only facts will be given; the FDA will attempt to delete opinion. ¶ 20, 39 *F. R.* 44604.

[29] 21 U. S. C. 335.

serious difficulty with the FDA, what the nature of the difficulty was, and how the company attempted to resolve it.

In addition, if one is interested in acquiring, or merging with, another company, it will be possible to obtain correspondence with that company following any factory inspections, any recall or detention requests, any notices or refusal to allow importation of a product, all regulatory and information letters, as well as certain factory inspection forms.[30] A review of this correspondence and documents should tell a great deal about the company's policy and its relationships with the FDA. Unfortunately, under the current regulations, the establishment inspection reports prepared by FDA inspectors are not disclosed until the matter is closed. Presumably, however, the conclusions reached in such reports could be obtained by reviewing regulatory letters and the like.[31] If any of this correspondence indicates that there have been oral discussions, either by telephone or at the FDA, it may be possible to obtain copies of memorandums of those discussions—additional information which may complete the data obtained before.[32] One caution in connection with these documents—while you will be able to obtain a great deal of information about other companies and products, the FDA will protect individuals, especially in serious situations such as 305 hearings.[33]

More Reliable Decisions

In sum, by use of these documents (and others not covered) one will be able to learn a great deal about companies under consideration for merger or acquisition. It will no longer be necessary to speculate as to what regulatory problems companies may be having. This will make more reliable the decision of whether or not to buy. Substantially the same information described before will also be available about products.

To this point we have discussed the many opportunities available under the FDA's Public Information Regulations. These opportunities are so extensive and varied that it may seem hopeless to discuss how a company can protect its own privacy and the confidentiality of its documents on file at the FDA. And, indeed, it may be

[30] Reg. 4.64, 39 *F. R.* 44647; Reg. 4.101, 39 *F. R.* 44650; and ¶ 110-114, 39 *F. R.* 44616-7, ¶ 151-163, 39 *F. R.* 44622-23.

[31] ¶ 156, 39 *F. R.* 44622.

[32] Reg. 4.104, 39 *F. R.* 44650.

[33] There is an unfortunate twist to this, however. If a request for a Sec. 305 hearing record about a particular individual is made, his name will be deleted —and the records given! ¶ 18, 39 *F. R.* 44604.

necessary to recognize that much of what is now on file at the FDA is available to anyone who asks for it, and that dealings in the future will be much more public than they were in the past. However, there are measures that can be taken.

For documents already on file at the FDA there is little to be done unless a company is interested in reviewing all of its past submissions and determining which contain trade secrets, confidential information, information about pending INDs or the like, and then advising the FDA of the company's position on each subject. Such an extensive effort is probably not worth the time and the FDA is not asking that it be done.[34] For records to be submitted in the future there are steps that can be taken to protect whatever legitimate interests there may be. Naturally, this requires some understanding as to what those interests are.

Trade Secrets

The most important documents that are protectable are those containing trade secrets or privileged confidential commercial information. These terms are defined in the regulations. While it would be inappropriate to enter into an extensive analysis of either the law of trade secrets or the federal statutes dealing with trade secrets and confidential information, it is worthwhile to note their scope.[35] A trade secret can be any formula, pattern, device or compilation of information that is used in one's business and which gives an advantage over competitors who do not know it. Confidential information is information used in one's business and is of a type usually held in confidence and not disclosed to the public.

[34] ¶ 9, 39 *F. R.* 44603. The FDA does say that if a company has a record at the FDA which it regards as a protectable trade secret or confidential information and these regulations appear to dispute that conclusion, the company should promptly file a declaratory judgment action. ¶ 63, 39 *F. R.* 44609.

[35] Reg. 4.61(a), 39 *F. R.* 44647, adopts the definition of trade secrets from the Restatement of Torts, ¶ 80, 39 *F. R.* 44612, and concludes that the terms "trade secrets" and "confidential information," as used in various Federal Statutes (for example: 18 U. S. C. 1905 and 21 U. S. C. 331(j)), while different, are sufficiently similar so that they can be treated as identical. ¶ 78, 39 *F. R.* 44611-2. The FDA cites no authority for this conclusion and it could lead to trouble. The distinction may be, as the FDA says, "subtle," but subtle differences can cause major arguments. The Agency itself notes a major difference between the two; trade secrets depend upon competitive advantage while confidential information does not. ¶ 289, 39 *F. R.* 44614.

These definitions are necessarily broad generalizations and, while the FDA does set out some specific items that it regards as trade secrets, we are largely left to our own resources to decide what are trade secrets or confidential information. The best recommendation for approaching this problem and protecting valuable rights is in three parts: (1) determine if the particular item of information truly is of unique value to the company; (2) if so, mark it as such and tell the FDA the reasons for that conclusion; and (3) in determining trade secrets, don't overdo it. If a company attempts to classify too much data as confidential or as trade secrets, it will lose credibility and thus threaten truly valuable documents. So far as marking documents is concerned, the FDA says that marking a document "confidential," of itself carries no weight. Mark it anyway and, if necessary, provide a statement as to why the information is a trade secret or otherwise confidential.[36] If an item is a trade secret because the FDA specifically says so in a regulation, or in the preamble, cite it. If an item is regarded as a trade secret or confidential for some other reason, state it. In other words, tell the FDA what you want to protect. Only in this way can one be assured that the FDA has been put on notice—notice which, under the FDA's own regulations, may be crucial.

Issue of Confidentiality

It may be crucial because, under these regulations, the FDA determines what is a trade secret or confidential and informs the company involved that its records may be released only if, in the FDA's view, the issue of confidentiality is a close one.[37] If the FDA decides that a record does not contain a trade secret, that record will be released, on request, and the owner of it will never know what happened.[38] By marking documents, by citing appropriate regulations or by providing a reasoned argument about why a document is entitled to trade secret status, one may at least trigger the "close" question regulation and so learn of a proposed disclosure before it happens. Then, if the facts warrant, legal action can be taken to protect one's rights.[39]

[36] Reg. 4.27, 39 *F. R.* 44644; ¶ 38, 39 *F. R.* 44606.

[37] Reg. 4.45, 39 *F. R.* 44646; ¶ 62, 39 *F. R.* 44609.

[38] The FDA does have a publicly available file of all requests for records and responses. Reg. 4.31, 39 *F. R.* 44644; ¶ 42, 39 *F. R.* 44607. However, since this file is only at the FDA headquarters in Washington, its utility for companies interested in their data is questionable.

[39] See Reg. 4.46, 39 *F. R.* 44646; ¶ 96, 39 *F. R.* 44614.

The Agency does list many types of information that it agrees are entitled to trade secret protection. If documents containing these categories of information are clearly identified, they should be protected without further effort. They include:

(1) manufacturing processes and controls, including the processing records for the low acid foods;[40]

(2) sales, distribution data, customer lists and sales demography data;[41]

(3) for a new drug, both animal and human as well as antibiotics, both quantitative and semi-quantitative formulas, while for all products, their inactive ingredients.[42]

Additionally, the existence of an IND or NDA in a trade secret is protected, as are the full reports of safety and efficacy in such files, including even in more limited cases, the protocols by which the products were tested.[43]

Public Disclosure

As a reader of the regulations can appreciate, trade secrets constitute a great amount of data and so protecting them requires care, because any public disclosure removes that data from trade secret status. This means care must be taken in speeches, articles, releases to the financial community—even in casual conversation. If a competitor hears such talk or reads in the trade press or scientific journals about a company's work, he can get the full story later from the FDA. Good controls of all public contacts are therefore essential to trade secret protection. This has always been true but it is even more so now that the largest depository of that information—the FDA—has said that it will release any trade secret once there has been a public disclosure.

There are one or two other techniques that may help. Certain officials at the FDA have to write memos of all conversations they have with outsiders and these are available.[44] If trade secrets, or the like, are discussed with these officials they should be told so. Don't leave

[40] ¶ 201, 39 *F. R.* 44628; ¶ 296, 39 *F. R.* 44640.

[41] ¶ 292, 39 *F. R.* 44640; ¶ 160, 39 *F. R.* 44623.

[42] Reg. 135.33a(g)(3), 39 *F. R.* 44654; Reg. 314.14(g)(3), 39 *F. R.* 44655; Reg. 431.71(f)(3), 39 *F. R.* 44636; ¶ 92, 39 *F. R.* 44614; ¶ 285-6, 39 *F. R.* 44639.

[43] See ¶ 249-257, 39 *F. R.* 44634; ¶ 279, 39 F. R. 44639. The names of investigators involved with a particular IND are also regarded as a trade secret. ¶ 241, 39 *F. R.* 44633.

[44] Reg. 4.104, 39 *F. R.* 44650. The FDA plans to publish regulations announcing who these officials are and when memos are required. ¶ 174, 39 *F. R.* 44625.

the issue in doubt. Also, the regulations provide that both sides to a conversation can submit memoranda of what was said and, if a request is made for one, both will be given.[45] This technique can be used in some cases to alert the FDA that trade secrets are involved and also so that, if disclosure is made, at least both versions of what happened will be made known. Finally, and doubtless the most obvious technique of all, companies can limit the information given to the FDA to exactly what is required and nothing more. If a trade secret does not have to go to the FDA, do not send it. What the Agency does not have, it cannot release.

These have been only the highlights of the problems and opportunities under the new Public Information Regulations at the FDA. The next few years should unfold many more possibilities. **[The End]**

FULL HEARING ORDERED ON NDA DENIAL OF THYROID DRUG

The Food and Drug Administration (FDA) has been ordered to conduct a full evidentiary hearing, the first since the 1962 drug amendments, on a new drug application which the FDA refused to approve for a failure on the part of a thyroid drug manufacturer to demonstrate its safety and effectiveness. The U. S. Court of Appeals for the District of Columbia in *Edison Pharmaceutical Company, Inc. v. Food and Drug Administration et al.* found that the material submitted by the manufacturer met the threshold evidentiary requirement established by the United States Supreme Court in *Hynson, Wescott and Dunning v. Richardson* (461 F. 2d 215, *affirmed* 412 U. S. 609). The question of whether double-blind tests comparing the manufacturer's thyroid drug with the thyroid extract, levothyroxime, would be too dangerous to perform or would pose a risk of death to patients was deemed by the Court as a sufficient material fact in dispute, as required by statute, to require a full evidentiary hearing. The Court further ordered the FDA to hold the hearing on all relevant issues relating to approvability of the NDA, regardless of which way the threshold issue was decided.

CCH Food Drug Cosmetic Law Reporter, ¶ 38,017

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[45] ¶ 176, 39 *F. R.* 44625.

Drug Company Concerns and Opportunities— How We Will Cope

By WARREN E. WHYTE

Mr. Whyte Is Senior Attorney of Regulatory Affairs of Abbott Laboratories.

CERTAINLY ALL OF US badly need an educational session on these novel, complex and confusing Freedom of Information (FOI) Act rules. My first *caveat* is that I am speaking as an individual lawyer and am in no way stating the policies or positions of Abbott Laboratories.

In ruminating on these rules, I must confess to mixed emotions. I would assume that most people are in favor of freedom of information, open government, and the principle that we should be able to find out what the government is doing and why it is doing it. Recent history in Washington would demonstrate that secretive government is not to the benefit of anyone. However, in my opinion, there must be certain reasonable limits on the public disclosure of the activities of individuals and organizations if worthwhile goals are to be accomplished in reasonable periods of time. I think the Food and Drug Administration (FDA) in these regulations has exceeded those limits in certain respects.

I would also like to comment on the extreme complexity of these regulations and the problems that those complications will lead to in the implementation of the rules on a day-to-day basis by the personnel of the FDA, and of the industry. In my more than 20 years of working for and dealing with the federal government, I am hard put to recall any government pronouncements as complicated and as confusing. It is not simply the fact that the regulations and the explanatory preamble, which I regard as an integral part of the regulations, cover 56 pages in the *Federal Register*, but that when one attempts to

read and analyze this treatise, a good many of the sections and paragraphs refer to, incorporate, are limited by or have exemptions, in other sections or paragraphs. After turning to the other section or paragraph in question, one is often faced with additional referrals, incorporations, exceptions or exemptions. While I personally find this an interesting intellectual challenge, I must also reflect on the degree of comprehension and mastery of this maze by the FDA and industry personnel who will have the task of implementing these regulations. Since we are dealing with valuable trade secrets and confidential information of manufacturers and with an almost infinite number of communications between the FDA and the regulated industries, I cannot help but wonder how these individuals are going to be able to fathom and follow the regulations which have boggled the minds of leading lawyers in the food and drug field—at least up until the time of this briefing session. Not only are the 56 pages of regulations perplexing enough, but the FDA personnel are also going to be faced repeatedly with the difficult consideration of what constitutes a trade secret or confidential commercial information. I, for one, cannot unilaterally determine at my company what safety and effectiveness information constitutes a trade secret or confidential information without checking with our people who have been involved in the development and usage of that information. I must confess that I am a little mystified as to how the public information personnel at the FDA are going to make those decisions without consultation with the manufacturer who submitted the information.

Formal Submissions

One of my major concerns with these regulations is the various rules set forth as to the release of data contained in our formal submissions (such as Investigational New Drugs (INDs), New Drug Applications (NDAs), antibiotic forms, and biological license applications) primarily because such submissions usually contain the most valuable and important information that a pharmaceutical manufacturer submits to the FDA. These rules can best be summarized by stating that as to 505 new drugs and 512 new animal drugs, the FDA will release a summary of all safety and effectiveness data in the "NDA file." The summary, incidentally, will be written or revised by the FDA. The FDA will also release from a NDA file all safety and effectiveness information that has been "previously disclosed to the public." It will also disclose the existence of an IND or NDA if that fact has been "publicly disclosed." The FDA's concepts of public disclosure, set

forth in Section 4.81, make for interesting reading. The FDA will also release all safety and effectiveness information in a NDA file if:

(1) the NDA has been "abandoned";

(2) a final determination is made that the NDA is not approvable;

(3) approval of the NDA is withdrawn;

(4) the FDA determines the drug is not a new drug; or

(5) the FDA determines that others may market the drug without such safety and/or effectiveness data.

As to antibiotic and biological submissions, the FDA will release *all* safety and effectiveness information.

I think we all have to be concerned about the fact that the FDA is now releasing portions of our IND, NDA, INAD, New Animal Drug Application (NADA), antibiotic and biologic submissions. I certainly hope, under these involved regulations, that mistakes do not occur and that some of our trade secrets and highly confidential information are not inadvertently released. The manufacturing portions, particularly, of such submissions may include trade secrets literally worth a fortune. It would be nothing less than disastrous if this procedure should allow such information to be disclosed. I think we all felt more secure when the FDA treated the entire file on such submissions as highly confidential.

Across-the-Board Rules

The FDA's across-the-board rules as to release of all safety and effectiveness information, or summaries thereof, are bound to cause problems. (I must admit that I cannot comprehend the distinction between data on new drugs and new animal drugs on one hand and data on antibiotics and biologicals on the other). While pharmaceutical manufacturers will sometimes permit the publication of such data as a contribution to scientific knowledge, much of it is kept in confidence. Often such data constitute trade secrets and/or confidential commercial information. In an IND, as just one example, are set forth extensive data on the animal studies that have been performed at substantial expense. If such information is obtainable, a potential competitor will be able to prepare an IND at considerably less expense by avoiding the efforts and work we had to undertake in order to devise the protocols and studies for doing the necessary safety work. The same considerations may apply to clinical studies.

Even if clinical and animal studies might not be trade secrets, they were certainly submitted to the FDA in confidence, which leads to another basic concern with these regulations. That is, they make available for public disclosure safety and effectiveness data submitted in the past when it was the policy of the FDA to hold such submissions in strict confidence. If the reversal of this policy set forth by these regulations were to apply only to future submissions, our concerns would be less since we would at least be on notice that the FDA was going to disclose our data. We could then attempt to handle it accordingly. However, to apply public disclosure to all past submissions is, in effect, to change the rules in the middle of the game. This raises some serious questions in my mind as to the legality of such a policy. Nor can it be said that such a change in policy has been brought about by the enactment of the FOI Act, since that statute was enacted in 1966. This policy of disclosing safety and effectiveness data in drug submissions has been adopted only recently.

I think my concerns—and evidently those of other pharmaceutical manufacturers—as to the disclosure of information in our submission files could probably be solved by the FDA on a relatively simple basis. That is, the Agency should notify us when someone requests information from those files. In Section 4.45, the FDA states that it will only give us such notice when the Agency unilaterally determines that the confidentiality status of the information is "uncertain." Notice of every request would at least allow us to know that the FDA may be considering the disclosure of our information. This would give us an opportunity to evaluate its confidentiality status and to inform the FDA of our position and reasons. We would also then know, after reading the ten-day letter of response, if the FDA intended to disclose our data, and we would have the opportunity to file suit, if necessary, *before it was disclosed*. Thus, we would be put in the same posture as when the FDA notifies us that the situation is "uncertain." I do not see how the giving of such notice would be much of a burden to the Agency. It seems to me that whenever the Public Records and Documents Center at the FDA receives a written request for such information, it would be a simple matter to make a copy of that request and send it to us. Short of such a simple notification system, I see no alternative except for all of us to check frequently with the public information office at the FDA to see who is requesting what information from our submissions.

The FDA has also stated that it will release all safety and effectiveness data in any NDA that has been "abandoned," or when the

FDA has made a final determination that the NDA is not approvable. I do not know how the FDA determines that a NDA has been abandoned, but it is certainly not unusual in the NDA procedure for a substantial period of time to pass without the submission of additional information by the manufacturer. Perhaps the way to cope with this situation is to establish a system whereby you periodically notify the FDA in writing that you have not abandoned a NDA.

The FDA policy of releasing all such information from a NDA which has been declared not approvable is even more troublesome. As many of us know, it is probably the rule rather than the exception for the FDA to issue a nonapprovable letter sometime in the lengthy life of a NDA. This nonapprovable status may exist for only the period of time that it takes the manufacturer to respond to the requests for information in the nonapprovable letter. But during that period all of the safety and effectiveness data in that NDA could be released to anyone who was timely enough to request it.

A different area of concern is the FDA's policy that all correspondence, all minutes of meetings and all summaries of oral conversations, telephonic or otherwise, will be immediately available for public disclosure. I am sure that many of us who have numerous dealings with the FDA on a wide variety of subjects are indeed apprehensive that all such discussions are going to be reduced to writing and released, along with all correspondence, to anyone who can afford the price of a copy. I believe that it is going to be very difficult to conduct our day-to-day business in such a goldfish-bowl atmosphere. I am sure that the fact that all of these communications, written and oral, are going to be publicly available can only hinder and constrain communications between industry and the FDA, by reducing the candor and straightforwardness of our meetings, discussions and correspondence.

While I only express trepidation about the policy of revealing correspondence and records of discussions, I have much stronger feelings concerning the policies that all investigatory and enforcement files will be released. Such disclosure will be made either when the file is closed or when a record has been disclosed to some member of the public, including the subject of the investigation or enforcement action. The FDA states that it will release factory inspection reports, recall requests, regulatory letters, 2275's, 483's, and similar records. They will also release the records of a 305 hearing and of an investigatory file. There is some solace in the fact that files pertaining to a contemplated criminal prosecution of an individual will not be released. While

I share the FDA's concern for the reputation of human beings, I would like to point out that businesses have reputations which are also highly important. The problem with the release of such records is that they are usually one-sided and uncontroverted descriptions and evaluations of a situation by certain individuals at the FDA. The fact that, in the overwhelming majority of FDA investigations, the government does not see fit to institute a legal proceeding would indicate that no violation of law has occurred. That such unilateral allegations will now be made public should shock the conscience of anyone concerned with fairness and fair play. We would be naive to think that the contents of such records will not receive widespread and critical publicity, and that the legal presumption of innocence will protect the reputation of a company in such situations.

Having discussed just a few of my concerns with these regulations, let me conclude with a few thoughts and suggestions as to how a pharmaceutical manufacturer might attempt to cope with them. Since such a relatively short period of time has passed since the publication of these regulations, I must again admit that I am not particularly advanced in my thinking as to how we will cope.

I would think that the first step in coping would be to establish a system to monitor who is requesting what information concerning your company, and to follow the handling of such requests by the FDA. Since the FDA has declined to send us copies of the requests pertaining to our companies and products, it seems that we have no alternative but to establish a system whereby periodic checks are made in Rockville at the Public Records and Documents Center. I think that if the manpower is available, such checks should be made at least weekly since, under the timetables established by the regulations, information can be released very quickly. Once it has been discovered in the log that a request pertaining to your company has been made, the request must be followed in order to examine the FDA's ten-day written response setting forth which records will be released and which will be withheld. Eventually, you will want to check to see the copies of the records actually released.

Difficult Task of Educating

We face a rather difficult task of educating and organizing our own people, particularly as to how we will communicate with the FDA under these new regulations and as to what information we will furnish. I suggest that this initially involve the preparation and dissemi-

nation of a memorandum to all concerned personnel, attempting to explain these regulations in a simplified and understandable manner. The next step I would suggest is to conduct educational seminars for those individuals in your company who have the responsibility for dealing and communicating with the FDA. I think you would want to review in order the many types of documents that are routinely submitted to the FDA and decide whether your practices should be changed in view of the potential public disclosure of those communications. Discussions should also take place concerning the various types of meetings held with the FDA, both in Washington and at manufacturing locations, as to any changes in procedures in view of the new regulations. Particular attention should be paid to trade secrets and confidential information, and as to how you will notify the FDA representatives that the information communicated falls in that category.

Another coping procedure that has occurred to me is that, in view of the FDA's refusal to notify you when information may be released from submission files, you may want to go back and review your past submissions, particularly the ones that are of substantial commercial value. Then you may want to write to the FDA to specify the information you consider to be confidential and the reasons for it. I am aware that Section 4.27 of the regulations states that the FDA will not honor any claims of confidentiality, but perhaps if such letters were included in your submission files, the FDA employees reviewing them in response to a request would at least know your position as to why such information is not subject to disclosure. I am sure that this will not be a popular suggestion because it will be an onerous task. But perhaps there is no other practical alternative to protect our more valuable trade secrets and confidential information.

Finally, for the benefit of the lawyers in the audience, I would like to point out that Section 4.46 of the regulations states that, if the FDA disagrees with your position on the disclosure of information, you are allowed the extensive period of five days to file suit to enjoin such a disclosure. Also, in those instances where the FDA does not notify you of contemplated disclosure, and you learn of it only through monitoring the log, then your time for filing suit is even more limited. Therefore, I suggest that all attorneys, in view of the very short time allowed, draft a model complaint, with a supporting memorandum, which can be used in a federal district court on short notice.

[The End]

Food Company Concerns and Opportunities— How We Will Cope

By GARY A. SUNSHINE

Mr. Sunshine Is Director of the Regulatory Law Department of ICI United States, Inc.

THIS TOPIC has a simple enough title. Yet, when I inquired of my colleagues at various food companies as to their feelings with regard to this subject, the reactions were mixed. While some people expressed concern, others said that the regulations had very little effect on their operations or they were too busy coping with the Federal Trade Commission proposal on food advertising. One attorney indicated that it had taken all of his time just to annotate the regulations to the 307 preamble paragraphs. Others indicated that they were waiting for the Food and Drug Law Institute briefing session to learn about concerns, opportunities and coping.

These reactions are not surprising even though the Food and Drug Administration (FDA) has told us that it has been following the policy established by the regulations for more than two years. While the basic policy may be unchanged, the 56 *Federal Register* pages of December 24, 1974 did include some changes from the earlier publication and it is anticipated that the FDA will make some additional changes. Furthermore, court challenges are yet to come.

I believe that the conclusion to be drawn from the foregoing is that at the present time there is a lack of understanding of the regulations in the industry. However, industry is not alone. From all that we have been able to learn, there is only one person at the FDA who completely understands the regulations. A representative of one food company told me that more than two-thirds of the time spent at a

recent meeting at the FDA was devoted to a discussion of Freedom of Information (FOI) and its impact on the matters that the company had hoped to cover at that meeting.

Concerns

Certainly the lack of understanding and confusion that presently exists will diminish with the passage of time. Of greater concern to food companies is the fact that the net effect of the regulations will be to inhibit free and open communication between industry and the Agency. At one time or another, each of us has been confronted with a situation that could result in a problem for our company or client. In the past, there was seldom any hesitation before deciding to discuss the problem with the Agency to develop a reasonable means of dealing with the situation consistent with the public welfare. Today, in view of the new regulations, we will think twice before making any unnecessary disclosures to the Agency.

Another facet of the same problem confronts the food industry with regard to new technological developments. For many years it has been the practice of major companies in industry to consult with the FDA periodically during the development stage of a new research project. It has not been unusual for a company to submit preliminary data to the Agency, discuss that data and agree on the next step to be taken in the program. The discussions often include consideration of the types of additional studies to be conducted and the details of the protocols. Under the new regulations, companies involved in such programs will be hesitant to meet with the Agency because, in many cases, the mere fact of the company's interest in the particular field of research is often considered to be confidential commercial information.

I believe that this potential breakdown in communications is the most significant concern of the food industry. Certainly the inhibition of the free flow of information from the industry to the FDA inures to no one's benefit. It results in slowing down major developments and reducing the Agency's information base.

We in the food industry, as people in all of the regulated industries, are also concerned about the opportunity that these regulations present for the occurrence of sensational publicity in the lay media based on fragmentary and often misunderstood or misconstrued information obtained under the FOI regulations. This problem is particularly acute with regard to toxicological data which laymen are not able to interpret. It can be argued that such events have occurred

prior to the issuance of the FOI regulations. However, it is obvious that the opportunities for such events to occur have been greatly multiplied. I do not contend that this is sufficient reason to justify any change in the regulations. Nevertheless, it is a basis for very serious concern.

While it is not my responsibility to comment on or criticize the regulations from a legal point of view, I would like to say a few words about one provision, from a practical point of view, because it is of great concern to the food industry. That provision is Section 121.51(h)1. It reads in part:

"The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after notice of filing the petition is published in the *Federal Register* or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:"

There follows a listing of the types of data that will be disclosed including "all safety and functionality data and information submitted with or incorporated by reference in the petition."

Food manufacturers are concerned with this provision for several reasons. The specific details of how to effectively use a food additive in a particular food are developed at great expense to the manufacturer. Making this information freely available to others will result in savings of both time and money in competing with the developer of the data. In the case of many food additives, the safety data may also be considered confidential commercial information. I am thinking particularly of the situation in which a company develops a multipurpose food additive and conducts all of the necessary toxicological studies. A food additive petition is filed for use "A" of the product and ultimately a regulation is issued. If another company which fabricates finished foods wishes to use the additive for use "B," it would have to come to the manufacturer that developed the toxicological data to obtain authorization to utilize that data in a petition for use "B." In return for the use of the data, the manufacturer of the fabricated food would probably purchase a substantial portion of the requirements of the additive from the company that developed the data. Under Section 121.51(h), that safety data would be made available when the notice of the filing of the petition for use "A" appeared in the *Federal Register*. Therefore, the company that contemplated use "B" would no longer be compelled to go to the company that developed the toxicological data. Subsequent purchases of the additive could be made from any manufacturer of the additive.

We have still other concerns, centered around the timing for the release of the information, about this same provision. Specifically, we are concerned about the release of data upon the appearance of a notice of filing in the *Federal Register* or after the mailing of the letter containing a notice of deficiency. Making the information available at these times will effectively destroy valuable lead time that the petitioner would otherwise enjoy while competitors develop the necessary functionality data. It could also result in the disclosure of a large food manufacturer's interest in a particular additive where the petition may have been filed by a food additive manufacturer in its own name but including data supplied by the end user. In these situations, competitors will "jump on the bandwagon" at an early date and will be in a position to market their products upon publication of the final order, the same time that the primary manufacturer commences marketing.

These are some of the major concerns confronting the food industry. As implementation of the regulations continues, additional concerns undoubtedly will surface.

Opportunities

What are some of the opportunities presented by the regulations? William Pendergast has already told us how to go about obtaining a competitor's data.[1] While all food companies can, and probably will, take advantage of this opportunity, the data will be of most value to those companies that have very little involvement in research and development. The innovative companies that expend great effort in discovering and developing new and improved products will be only marginally benefited. On balance, the innovative companies will probably be giving up more data than they will receive.

Perhaps the most significant opportunity presented by the FOI regulations is the opportunity for self-improvement. The availability of the FDA manuals listed in Paragraph 193, the FDA regulatory action levels, and the administrative enforcement records provide us with an opportunity to focus on those areas which are of prime concern to the Agency. Knowing the areas that the FDA considers critical from a public health standpoint and what conduct the FDA considers acceptable enables responsible industry to strive for a level of performance that exceeds normal expectations. Any such improvements in our performance as an industry will obviously benefit the consumer.

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[1] See article on page 326.

While the regulations do provide new opportunities for industry, it seems that at the present time the concerns of the food industry outweigh the obvious opportunities. Hopefully, the balance will shift over the next several months.

Coping with the FOI regulations in the food industry will follow the same principles as in any of the other regulated industries. The first step is an internal educational program to familiarize people within the individual food companies with the policies established by the regulations and reasonable steps to be taken in protecting the confidentiality of company data. As a part of any such internal program, many companies will be reviewing their policies and procedures for dealing with food and drug inspectors as well as with other Agency contacts. In the past, many companies have been quite open with inspectors and have voluntarily provided information beyond that required under the statute. This policy will require rethinking in light of the new FOI regulations.

A second step to be taken in coping with FOI is to increase the use of third parties as contacts with the Agency in order to limit the exposure of individual companies and their trade secret or confidential commercial information. I am sure that, in the months ahead, the FDA will be confronted by an increasing number of hypothetical questions posed by private attorneys.

A third step to be taken in coping with FOI is a defensive watchdog effort on the part of the individual companies. The log of FOI requests must be reviewed on a regular basis in order to determine if anyone is attempting to obtain data or information concerning your company or its products since the regulations provide for notice to the company only in limited circumstances.

While my remarks may indicate a feeling of dismay within the food industry concerning the FOI regulations, my own personal view is more optimistic. I believe that, as the Agency learns to understand and administer the regulations and as the industry learns to understand and live with the regulations, life will not be as difficult as it may seem. I base this view on hearsay evidence with regard to how the FDA interprets some of the standards set forth in the regulations and how the Agency intends to apply them. Unfortunately, the regulated industry cannot rely on such good faith intentions. The regulations must be revised to conform to practice. I sincerely hope that in response to the many comments submitted, the Agency will modify the regulations so that they accurately reflect reasonable standards.

[The End]

Cosmetic Company Concerns and Opportunities—How We Will Cope

By JACK L. MOST

Mr. Most Is Vice-President of Legal Affairs of Revlon, Inc.

I AM GOING TO PROVIDE COMMENTS and reflections on the methods the cosmetic industry is, and will be, using to deal with the newly enacted Food and Drug Administration Freedom of Information (FDA FOI) Regulations. Obviously, there has been little or no experience in dealing with the newly enacted regulations by cosmetic industry companies. However, industry companies are familiar with the methodology of submissions to the FDA, particularly under the industry voluntary submission programs.

The new FDA FOI Regulations recognize the special nature of the existing cosmetic industry voluntary submission programs whereby companies, pursuant to regulations initiated by the industry and developed with the FDA, regularly submit to the Agency product ingredients and raw material composition statements. On a semi-annual basis, except in unusual situations, reports of cosmetic product experiences, sometimes commonly known as "adverse reaction" reports, must be submitted.

The FOI regulations provide special treatment for protection of information provided to the FDA on a voluntary basis pursuant to these programs. A caution to the cosmetic industry is that trade secret and confidentiality treatment protection for the voluntary submissions must follow the strict procedures of Section 4.44, "Presubmission Review of Request for Confidentiality of Voluntarily Submitted Data or Information." This is the exclusive method under

which the regulation companies may request that data and information submitted voluntarily be held confidential and not for public disclosure. If the FDA rejects the company claims for trade secret or other confidential status, such material may be totally withdrawn from the FDA.

Unknown Interpretation

What appears to be troubling cosmetic companies at the present moment is the yet unknown interpretation by FDA officials of what constitutes trade secrets or confidential information. Of course, cosmetic companies will have to develop a *modus operandi* so that employees do not divulge to any member of the public information, orally or in writing, that the company later requests to be held as a trade secret or confidential. In this case, the public can include suppliers, customers, the financial community or other unrelated persons. I suspect that lawyers in the cosmetic companies have been, and will continue to be, providing counseling to company officials in this area to make it clear that prior lawful disclosure (subject to certain exemptions) will bar a subsequent claim for confidential treatment. Assuming that the companies can properly adjust to this restriction and, further assuming that an easy flow of presubmission review of confidentiality requests is established, we remain with the gnawing problem of what constitutes confidential information. Some understanding of what the FDA concludes is trade secret or confidential has already been developed during the past two years of the operation of the voluntary filing programs. However, the experience to date is by no means conclusive.

Another troublesome aspect is learning from the FDA its plans to deal with information submitted on a voluntary basis, prior to the effective date of the new regulations, in instances where confidentiality had been requested. Does this mean that all pending confidentiality requests must now have new presubmission reviews? Does it mean that all previous grants of confidentiality continue to hold?

Another change that obviously will have to be made in dealing with the FDA is the method of utilizing informal conferences to discuss, with FDA staff, matters of either general industry interest or critical issues of a particular company. I am personally troubled by

the fact that a degree of mobility in dealing across the table with FDA officials in open give and take will be lost by the change of policy which includes public reporting of all meetings with industry officials. I think that, in the past, there have been many positive aspects of industry meetings with FDA officials about industry problems. These meetings have led to concrete solutions which have been a benefit to the government, to the industry and to the public. We will now find an undesirable formalization of relationships by virtue of the new regulations which will impede a mutual exchange of views on an informal basis. At this particular time, industry has not had an opportunity to evaluate appropriate alternative methods of dealing with the FDA on matters that properly should come before it. A good example of recent cooperative work is the development of the cosmetic ingredient labeling regulation. The FDA, after the initial proposal publication, had numerous contacts in meetings with industry representatives culminating in a reasonable regulation. Now no one is authorized at the FDA to give verbal commitments of confidentiality, so any materials presented at a FDA conference which are legitimate private company concerns, must have presubmission written clearance in order to be deemed confidential.

Special Protections

I understand from FDA staff that the cosmetic industry is expected to utilize the special protections in the regulations afforded to information voluntarily submitted to assure broader involvement and participation of industry companies in the voluntary programs. Presumably, the ability to have a presubmission ruling of confidentiality with respect to ingredients and the obligation of the FDA to treat as confidential product experience report information supplied by companies, including the company name, brand name and physician and patient name, will increase participation. Section 4.111, which prescribes confidentiality when information from product experience reports is submitted by a manufacturer, permits disclosure of all such information, except the submitter's name, when from a consumer. In the case of physician or hospital reporting, the submitter's and user's names may not be disclosed. This may lead to some headlining publicity, generally unwarranted, if a case or two is disclosed prior to the manufacturer having an opportunity to evaluate and put the report in proper perspective. I question the judgment of this permissible disclosure. I do support the industry voluntary programs and see

merit in the FDA's view that these regulations should now curb some of the concerns about legitimate confidential information.

Guidelines

The following represent suggested guidelines for cosmetic company officials to follow in dealing with information relevant to the FDA.

First: All submissons to the FDA under the voluntary programs must be carefully evaluated prior to submission to determine whether any of the information is a trade secret or is commercial or financial information which is privileged or confidential. If information deemed to be a trade secret or confidential is included with any voluntary submission, the prescribed procedure for presubmission review of voluntarily submitted information must be followed to insure preservation of the confidential nature of the information.

Second: The submitter of information cannot simply mark it with a designation such as "confidential" or "privileged." Such markings are inadequate to initiate a presubmission confidentiality review and will create no responsibility upon the FDA to deal with such information in the confidential manner.

Third: No one should rely on any oral assurances of confidentiality since no FDA employee is authorized to provide such voluntary assurance and the FDA will not offer these assurances. The only method available for confidential treatment of voluntarily submitted information is the presubmission review program.

Fourth: For the protection of confidential information, it is recommended that it not be mixed in a submission with information that is required to be submitted to the FDA under mandatory rules and regulations without a proper presubmission review of confidentiality requests.

Fifth: Company managements must be fully informed that, prior to any disclosure of company information to organizations, individuals or agencies outside the company, the person making disclosures should determine whether the information is a trade secret or is privileged or confidential. Management must understand that unless the person receiving the information stands in a confidential relationship, such as the company's attorney, accountant or advertising agency, or has an appropriate secrecy agreement, the opportunity to seek confidentiality at a later date upon submission of materials will be lost. **[The End]**

Panel Discussion

The Following Is Taken from the Transcript of the Panel Discussion and Question and Answer Session of the Briefing Session. Participating in the Discussion Were Joel E. Hoffman, Peter Barton Hutt, Daniel F. O'Keefe and Robert C. Brandenburg. Mr. Hoffman Is a Member of the Law Firm of Wald, Harkrader & Ross. Mr. Hutt Is Assistant General Counsel for Food and Drugs in the Food and Drug Administration. Mr. O'Keefe Is President of the Food and Drug Law Institute. Mr. Brandenburg Is Director of the Compliance Regulation Policy Staff in the Office of the Associate Commissioner for Compliance in the Food and Drug Administration.

Mr. Hoffman: It had originally been my intention, when I was asked to participate in this program and was assigned the topic of comparing the Food and Drug Administration's (FDA's) regulations with those of other agencies, to survey the full list of agencies which have regulations under the Freedom of Information (FOI) Act, beginning with the American Battle Monuments Commission (which were published about two weeks ago) and going right on through to the Zoological Park of the Smithsonian. But the moderator found out what my plan was, and cut me back to 20 minutes. So instead, I have picked out four specific aspects of the new FDA regulations and compared them with the regulations of agencies that deal with similar kinds of data (at least some of those agencies) in light of what I understand the basic statutory policy to be.

I think it cannot be denied that, as the regulations state, the basic statutory policy is toward disclosure except in the most limited kinds of circumstances. The Supreme Court has had very little opportunity to talk about the Information Act. But when it did last year in the *Bannercraft* case,[1] even though the information in question was held properly nondisclosable, the Court spoke of exemptions from the Act in very, very careful terms, and always as exemptions, specifically delineated exemptions. So I think that anyone who expects that there will be any cutting back on the basic thrust of disclosure, when

[1] *Renegotiation Board v. Bannercraft Clothing Co.*, 415 U. S. 1 (1974).

the Informative Act finally does get to the Supreme Court for a full-scale review, is in for a surprise.[2]

But on the other hand, those of you who think the FDA might have gone off the deep end in allowing disclosure may not have noticed the Consumer Product Safety Commission (CPSC). If you've only looked at the FDA, to quote the old phrase, "you ain't seen nothin' yet." It is instructive to compare the policies of these two agencies, the FDA and the CPSC, on two kinds of records: *First,* internal agency memos; and *second,* commercial data obtained from third parties, such as your companies and your clients.

The FDA says that intra-agency memos which disclose advice and recommendations will be released whenever this can be done without disrupting the Agency's activities.[3] That holds out a lot of promise. But in the entire list of specified categories of documents which are to be released on request,[4] the only group I can find which falls in the advice and recommendations category is documents which describe safety and effectiveness data for pre-1975 New Drug Applications (NDAs). Presumably, moreover, not all those will be made public—only documents sufficient to provide a description of the data. In other words, I don't think we'll get merely repetitive disclosure.

The CPSC's regulations are really no more specific than those of the FDA.[5] Like all exempt documents, the CPSC's internal memoranda will be disclosed in cases in which to do so is not prohibited by law or is not against the public interest.[6] But in practice, there is virtually nothing you cannot get from the CPSC, because the policy of that Agency is to require, apparently on pain of disciplinary proceedings, every employee to disclose every piece of paper generated by him or by someone else in the Agency that he happens to come across, no matter how preliminary, judgmental or candid that paper may be.[7] You are literally supposed to be able to walk into the

[2] Subsequent to the delivery of these remarks, the Supreme Court addressed one of the Act's most important exemptions (inter- and intra-agency memoranda) in *NLRB v. Sears, Roebuck & Co.*, 43 U. S. L. W. 4491 (April 28, 1975); *Renegotiation Board v. Grumman Aircraft Engineering Corp.*, 43 U. S. L. W. 4502 (April 28, 1975).

[3] 39 *F. R.* 44602, at 44615 (¶ 98) (1974).

[4] 39 *F. R.* 44602, at 44649-52, 21 C. F. R. Secs. 4.100-4.118.

[5] 39 *F. R.* 30298 (1974). The regulations are still mere proposals, never having been promulgated in final form after the time for filing comments expired.

[6] 39 *F. R.* 30298, at 30300 (proposed 16 C. F. R. Sec. 1015.15(b)).

[7] See generally the article describing CPSC "openness" policies by its General Counsel in the *Federal Bar News*, December 1974, p. 341, at 344.

CPSC's offices, wander around, walk up to some employee that you may know, ask him what he's got in his typewriter, and he's supposed to show it to you.

It may be hard to imagine how any group of mere mortals can function as a group under such scrutiny considering the inherent sensitivities, cautiousness and insecurities that plague us all. But even the CPSC has found that this regimen may be a little bit too stiff for it, and when put to the test, the Commission backed down (if only barely).

Let me describe the case in which this occurred. As you may be aware, the CPSC responded to the vinyl chloride controversy a few months ago by issuing a regulation declaring vinyl chloride aerosols to be banned as hazardous substances.[8] At the initial stages of this proceeding, which was conducted under Section 701(e) of the Food and Drug Act as the Federal Hazardous Substances Act requires,[9] the Agency put on the public record the briefing package prepared for the Commissioners by the staff, including the legal memoranda and the compliance staff memoranda that went before the Commission deciding whether to initiate the proceeding. When the so-called final order came out (the final order that is merely tentative), the briefing package underlying that order was made available, including the legal memoranda, the compliance memoranda and the policy memoranda.

After the final order was issued and objections were filed and denied, a petition was filed in the Court of Appeals to review the order denying objections and denying a hearing.[10] A request was then made by the petitioner under the FOI Act for the third briefing package; namely, the package before the Commission when it overruled the objections and denied a hearing. That request pended for some weeks, and was finally denied by the Commission by a vote of 3 to 2.[11]

Three of the Commissioners felt that, in this instance, it would not be in the public interest to disclose the briefing package, which (as described by the Commission in its opinion) amounted in sub-

[8] 39 *F. R.* 30112 (1974), 16 C. F. R. Sec. 1500.17(a)(10); objections overruled, 39 *F. R.* 36576 (1974); stayed, *Pactra Industries, Inc. v. CPSC,* Nos. 74-2902 et al., CA-9 (December 13, 1974). The author is counsel for the petitioner in that proceeding.

[9] Secs. 2(q)(2), 3(a)(2), 15 U. S. C. Sec. 1261(q)(2), 1262(a)(2).

[10] *Pactra Industries, Inc. v. CPSC, supra* note 8.

[11] Minute of Decision, CPSC, January 16, 1975 (unpublished).

stance to the general counsel's memo. Apparently to buttress their position, they released a copy of the general counsel's memo discussing the request. Two of the Commissioners, Chairman Simpson and Commissioner Newman, dissented.

They wrote a lengthy opinion explaining why they believed that intra-agency memoranda of this type, judgmental advice and policy recommendations, legally privileged (assuming that there is a traditional attorney-client relationship between the general counsel and the Commissioners) should have been disclosed.

The dissenting opinion sheds more light on the Commission's reasoning than anything in the formal minute entry of the Commission's decision. Commissioner Newman's opinion stated that three reasons had been advanced for nondisclosure of the general counsel's memo. One was the need to protect a challenged regulation in court—that is, why help the opposition? Her position was that if the regulation was invalid, it should be struck down; that the Commission had no business protecting an invalid regulation; and that a perfectly good way to help find out whether it was invalid was to look at the general counsel's memo.

The second reason that Commissioner Newman attributed to the majority was the need to protect the confidentiality of legal advice. Perhaps like the little boy who wondered why the emperor had no clothes on, she asked why the legal advice should be protected. The general counsel was being paid from the United States Treasury, she pointed out. He was a public servant. The public had a right to know what kind of advice he was giving the Commissioners.

And finally, a reason which Commissioner Newman did not discuss at any length but simply mentioned as one that might be advanced, was the need to protect staff views which are not shared in the end by the Commission. I suppose it's fair to say that, technically speaking, Commissioner Newman did not disclose the contents of the general counsel's memorandum. Those who have read her opinion don't have much doubt about what that memorandum said.

Now this is a regime under which every bit of legal advice received is laid out on the public record. For example, in the rule-making proceeding to ban certain bicycles as hazardous substances, a lawyer representing the bicycle manufacturers walked into an open briefing session, heard the general counsel deliver his advice to the Commission on what the weak points were in the proposed regulation and where it was susceptible to challenge, and subsequently filed his action

on the basis of the general counsel's advice.[12] This is government in the sunshine. This is open information. But whether the CPSC can continue to function under this kind of regime is, I submit, seriously open to question.[13] This is the Commission's policy. It is evidently not the FDA's policy.

Further, by way of comparison, let me turn to the problem of trade secrets and confidential commercial information. Putting aside the question whether one can argue with the FDA's definition of a trade secret, the regulations hold out the promise that the FDA will adhere strictly to the statutory prohibition against trade secret disclosure. It further appears that nontrade secret information of a commercial nature will be held in confidence if the FDA concludes, on what basis is not certain, that such information is customarily held in confidence by the industry (however "the industry" may be defined), and also if it concludes that the particular information being sought has not elsewhere been disclosed.

Now this may strike you as leaving a fair amount of play in the joints. But consider again the CPSC in the vinyl chloride matter. Prior to the initiation of its rule-making proceeding, pursuant to a grant of investigative authority contained in the Product Safety Act,[14] the Commission solicited information from all identifiable manufacturers of household aerosols, through the *Federal Register*[15] and through individual mailings. It requested information on whether vinyl chloride had been used in the company's products, when, how much, and just about everything else the company was in a position to tell them about its use of vinyl chloride. Having collected this information, the Commission found itself with a request from the Health Research group for all the information it had collected. This request also pended for some time, and the Commission finally determined to disclose a very substantial amount of its information.

Now it is not without irony, I suppose, that, in this case too, the way in which the CPSC disclosed its decision was by releasing the general counsel's memorandum on what the Commission was entitled to protect and what it was not entitled to protect. In that memorandum, the general counsel concluded, and the Commission evidently agreed, that, while some of the data fell in the trade secret category (although this has never been precisely defined for purposes of this Agency), the Com-

[12] See *Brown, supra* note 7.

[13] Subsequent to the delivery of these remarks, the Supreme Court raised much the same question in *NLRB v. Sears, Roebuck & Co., supra* note 2, at 4497.

[14] Sec. 15(b), 15 U. S. C. Sec. 2064(b).

[15] 39 *F. R.* 16511 (1974).

mission was entitled to balance the public need for disclosure against the public interest in protecting trade secrets. Nowhere mentioned in the memorandum was the statutory provision of the criminal code which makes it a criminal offense to disclose a trade secret once you determine what a trade secret is.[16]

And so the Commission disclosed the brand names of all products containing vinyl chloride, arranged by manufacturer, although it conceded that this amounted to disclosure of customer lists where the brand name was a private label and also to disclosure of the name of the supplier of the listed retail chain or other marketer of the products. Moreover, the Commission disclosed the production codes for all lots of household aerosols containing vinyl chloride, so that consumers could identify the hazardous substance. And finally, the Commission disclosed the quantitative formulas for vinyl chloride aerosol products insofar as the formula referred to vinyl chloride. It did not tell what else was in the products, but it did tell how much vinyl chloride had been used.

Now without getting into the question of whether any or all of this information was, in fact, a trade secret which should not have been disclosed, the point I want to make is that the Commission was totally untroubled by the statutory prohibition against disclosure. It was equally untroubled by any consideration as to whether the information should be disclosed, except for this Commission's view of what the public interest required. Now, I think as consumers, we might all say that it is very, very useful to know which of your spray paint cans sitting around the house contain vinyl chloride. But that, I submit, is not the question. At least it's not the only question. And fortunately, the FDA appears to have taken a somewhat broader view of its responsibilities, and not simply confined itself to making what comes close to an arbitrary decision as to what would be good to release and what would not be good to release.

On these two matters, I think it's fair to say that the FDA has stopped far from the outer reaches of information disclosure policy.

The third area of the regulations in which I'd like to compare the FDA's procedures with those of other agencies is the procedure for deciding whether a given bit of information is a trade secret or not. And here, it seems to me, the FDA doesn't come off quite so well. Even the CPSC, while holding out the threat, if not the promise, of

[16] 18 U. S. C. Sec. 1905.

total disclosure of anything that has been submitted to it, has a provision in its regulations for notifying the manufacturer or other person submitting the information ten days before the information is disclosed.[17] It appears that this kind of notification is contemplated in every case where a claim of trade secret or confidential status is made. There is no effort by the Agency, it seems, to decide which cases are close cases, which cases are doubtful cases, or in which cases the manufacturer is entitled to notice and an effective opportunity to bring the matter before a court.

Not so, of course, under the FDA's regulations. Under these regulations, no matter how passionately the person submitting the information may believe it to constitute a trade secret and to be protected by a criminal statute against disclosure, if the Agency believes that the question is not a close one and that the manufacturer is so far off base that it's not worth discussing, the information will be disclosed without notice to the manufacturer and without an opportunity to seek judicial relief. Even in the close case, the Agency holds out a promise of five days notification.

I think any lawyer would have to strain a bit in order to get into court with a well-drafted complaint on only five days notice. And I think that the company which does not have battalions of lawyers stationed in Washington, regularly reading the FOI Act files up in Rockville, or which does not have a man stationed there permanently, but which relies on some less expeditious means of communication to find out when its data is about to be turned loose, may have trouble getting itself together, making the decision, finding a lawyer, and getting a lawsuit filed.

An interesting comparison here can be drawn with the Environmental Protection Agency, whose regulations are now in somewhat of a limbo after the new amendments. They have released some new procedural regulations, and held out the promise of a new publication revising the substantive criteria for disclosure and exemption.[18] But looking to the regulations that have been in force over there for the last few years, there is an elaborate (some might say too elaborate) and very careful procedure for notifying a person who has submitted data. The submitter is notified at every stage of the process when a request for arguably exempt data is made.[19] He is notified when the initial recommendation is made at the staff level. He is notified when the

[17] 39 *F. R.* 30298, at 30300 (1974) (proposed 16 C. F. R. Sec. 1015.17(c)).

[18] 40 *F. R.* 10460 (1975).

[19] 40 C. F. R. Secs. 2.100 *et seq.*

general counsel makes his recommendation to the Administrator as to whether or not to disclose. There is even a provision which clearly requires follow-up, and appears to contemplate telephone follow-up, when written notification to the person submitting the data has produced no response. There is, in short, a very careful effort to be sure that data claimed to be confidential are not released, thereby mooting the entire question of confidentiality, prior to the company's having had an opportunity to go to court and get a judicial determination as to whether the data should be released.

Finally, there is the question of timeliness of actual production of the records. And those of you who've read the 307 paragraphs of the preamble to the FDA's regulations may have noticed that the Agency was very alert to the fact that the time limits under the amended FOI Act apply only to the decision whether to release data. They do not apply to the actual release of the data. As to that, the statute merely says that once a decision is made to release records, they shall be released "promptly." What that means is not a question I can answer.

But those of you who may expect the FDA by virtue of these regulations to turn the entire force loose on a battery of Xerox machines are going to be disappointed, it seems, because the regulations state that data will be produced and documents copied only at a pace which comports with the Agency's discharge of its statutory responsibilities. Now in the abstract, this is very difficult to argue with. I certainly wouldn't attempt to do so. I don't think any of you would.

But the question then remains, when are you going to get the data? In particular, the question remains, when you are going to get the data if you need it for use in some private litigation, or if you need it for use in administrative proceedings before the Agency? If there were such a thing as a hearing under Sections 505 or 701(e), considering that the Agency has no subpoena power, the only resort which one would have for getting the Agency's evidence would presumably be through the FOI Act. It might be possible to get to a court quickly enough to have the court say that the data had to be provided before the proceeding could go on. But that, of course, is a very chancy business, trying to enjoin an Agency proceeding; and there is absolutely no assurance in the FDA's regulations that a firm or a person requesting data, no matter how immediate its need, will actually be able to get that data in a timely fashion.

The CPSC, of course, has solved the problem by simply allowing you to wander around and pull it out of the typewriter. I suspect there

must be a middle ground here, and it must be a middle ground which does not require every Agency employee to turn himself exclusively to the business of copying the Agency's files. It would be useful if the FDA as well as other agencies would come to grips with the timeliness problem, in a way that goes beyond simply cautioning people not to expect too much.

Set up some sort of timetable. Set up a list of priorities. Set up circumstances under which a request will be guaranteed fulfillment within a reasonable time. Maybe that is the next chapter in these regulations. I would certainly hope so.

Mr. Hutt: Perhaps I could comment, from a few notes, on what appear to be the two main substantive issues that have been raised in many of the replies that have now been received by the FDA on the final order of December 24, and then discuss one procedural issue.

The two main substantive comments, as far as I can tell from reading the trade press, are as follows. First, a person affected by a record which is requested should be informed of that request before the record is released. That is probably the comment most frequently made.

The second substantive comment is that people have objected vehemently to Section 4.53, which provides that, unless a firm or other person who has submitted trade secret data is willing to index those data and to defend their nonreleasability in court, we will conclude that they have waived the right to have them defended, that is, they will have waived the right to declare those data as trade secrets, and we will release them.

The first issue is whether people should be informed when we are releasing information that affects them. I have jotted down roughly seven reasons why I disagree with this. I am sure that, if I spend another few moments, I could find another 17. First of all, such information is not required by the statute. Second, in my opinion, it is inconsistent with the statute. The statute as amended in 1974 flatly provides that we must decide within ten days as to whether we are going to release or not release the information. How we could ever make that decision and consult with people in the interim is utterly beyond me. Third, the burden that this would put on the FDA would be out of this world.

Mr. Brandenburg tells me we are now receiving requests under the FOI Act at a rate in excess of 5,000 per year. The number of

people that it would take to enter into negotiations of some type with the people affected by that release of information is staggering. As Mr. Hoffman indicated, with that kind of a system, we would basically be operating a research library and not a law enforcement agency.

Fourth, there is now available a Freedom of Information Services, Inc. For a small monthly fee, you can obtain same-day telephone alert of receipt by the FDA of FOI requests relating to a specified company and identified products. In addition, you can get a weekly index listing of all FOI requests and same-day alert of any nature, weekly index of regulatory letters, and all kinds of other things. This is a commercial service. I know of no one in the business world who would contend that the FDA should go into direct competition with a commercial entity. And I can assure you that we do not intend to do so.

Fifth, the regulations do provide in Section 4.45 that the FDA will consult with industry in close cases. The first question that someone will ask is: "What is a close case?" I am quite willing to let any of you put your hand to a definition. I will read the comments very closely to see whether, in addition to complaining about that, anyone has made any constructive comments as to how that could be more narrowly defined.

Obviously there are easy cases. If someone requests the Form 483 or 2275 on a factory inspection which shows insanitary conditions (for example, rats running around a food warehouse), there is no conceivable trade secret and no conceivable reason for consulting with anybody. Indeed, if someone were to walk in off the street and ask for a copy, it would be given on the spot without any questions asked. So if you object to the somewhat general term "close question" or "close issue," then I would suggest that it is incumbent upon you to find a better definition or a better term that will more adequately describe what I think is very, very clear in intent.

Sixth, a person can, if he becomes aware either through the FDA consulting him or through the new FOI services, the instant alert type of operation, sue the FDA to enjoin release of any information. We have pledged that, in absence of a court order, we will not release the information until the judicial proceedings are over. Once information is released, the judicial proceedings would be moot and we agree that would not be equitable.

Finally, there is no question but that if you do not like the categories that we are releasing or not releasing, which are laid out to the

best of our ability in these regulations, then you have the right to go to court right now to sue to enjoin our acting under these regulations. Everyone, for example, who submits a food additive petition is now on notice that, as of December 24, the safety and functionality data will be released, except in extraordinary circumstances which, as we say in the preamble, will be extremely rare. To my knowledge, we have found only one "extraordinary circumstance" situation in the last two and a half years. Now if you think that is wrong, is illegal, is not required, or we should be prevented from doing that, do not wait until we get a request for your safety and functionality data. You ought to go to court now and contend that the FDA is wrong.

We have been described, and I personally have been described, as litigious in making that remark. But ultimately, there is only one place where these issues can be resolved. I cannot personally resolve them. The Department of Justice FOI Committee cannot resolve them. The industry or the consumer groups cannot resolve them. Only a court can. What we are saying is: "Here are our rules. Anyone who wishes to contest them is perfectly entitled to go to court and do so. But if you do not contest them, do not be surprised when we implement them."

My conclusion is that the way that we have proceeded is entirely fair. It is, in my judgment, highly unlikely that they will be changed in the final regulation. I cannot say this definitely because I do not make that decision; the Commissioner does. But in all the discussion I have heard in the Agency on this matter, I have heard no one in the FDA top echelon suggest that that is something which should be changed.

Now let me talk more briefly about the entitlement to have the government defend trade secrets. You will be interested that, when it was first drafted, I considered writing it somewhat differently. It was going to provide that, if a person did not choose to come in, index and defend his trade secret data, then the FDA would submit the issue to the court without briefs or oral argument. Clearly, the FDA has no interest one way or another in either protecting or not protecting trade secrets. We couldn't care less. If Congress says and the courts say the public should have them, that is fine with us. If they say they should not, that is also fine with us. We have no axe to grind in this matter. The thought that we should be spending our time in court defending someone else's trade secrets rather than implementing the Federal Food, Drug and Cosmetic Act seems ludicrous to me. We have few enough lawyers and administrative people in the Agency to do the job that

Congress has asked us to do in terms of enforcing the law, and we see no point in spending an enormous amount of time in court defending the industry's trade secrets.

Now, as far as I am concerned, I would be perfectly happy to go back to the other formulation and say that we will simply write the court a letter, submit all the requested information, and let the court make up its own mind without briefing or oral argument. But it seems to me that that amounts to the same thing as the way it was included in the final regulation.

A procedural issue which was raised was that the final order was so different from the proposal that it should have been reproposed. Perhaps I just do not understand this issue very well. There is nothing whatever in the FOI Act that requires the FDA to put out any kind of a regulation. We could go about our business under the FOI Act releasing all records in our files, except for trade secrets which are prohibited from release and privacy data which, under the new Privacy Act, are probably also prohibited from release. But we could release everything else without one regulation, without informing anybody, without doing anything other than just going about our own business.

The reason we put out regulations was to tell everyone what we are doing. Most other agencies have put out their FOI regulations without any time for comment. They have put them out as final orders, and the public has not been allowed to comment at all. So we have gone much further than is required.

The statute is self-executing. If we had no regulations whatever, we would still be required to comply with it. In any event, whatever the arguments are about proposal-and-comment period and new proposal requiring new comment, we have in fact provided new time for comment. And there will be another final order, as the preamble states quite clearly. So if there were any defect, which in my judgment there was not, that defect has been cured by the additional time for comment. I must say this whole comment on the procedural issue simply escapes me.

There is one final question on a procedural aspect. When will the final order be issued? I can say that before I leave, which will be on May 16, that document will be drafted. I doubt that it will actually be in the *Federal Register* because that takes additional time.

My successor, Richard Merrill of the University of Virginia Law School, will therefore have to contend ultimately with the final resolution of this issue. And I am sure that he will have enormous good fun meeting with you in the future and discussing it.

Mr. Hoffman: This is really not in the nature of a response so much as an observation. I'm talking about the question of notice to a trade secret holder, which is really the same problem as the intervention problem that Peter Hutt raised. (Although I might say that I think the idea of soliciting intervention by the party supplying the data is a great idea. Whether it will work in practice, I don't know, but it certainly is innovative and worth a try.)

As to the notice problem, I listened very carefully to Mr. Hutt's reasons. The ones I got down don't really meet the objection. He says that you have the ten and twenty-day time limits. These regulations recognize on their face that the time limits do not apply to the actual production of data. The statute just says "promptly." Now, what is prompt? It seems to me a good argument could be made that "prompt" allows enough time, after the decision to release, to notify the party supplying the data that the decision has been made. So the time limit is really not a bar here.

Mr. Hutt then wanted to know how we articulate this kind of a general criterion of when data should be disclosed. The rat report, of course, is a very easy case. I think that anyone who came in and claimed trade secret data for that would be entitled to have his claim dismissed, so to speak, without a hearing. But I think a close question is something that one is in doubt about. I think a close question is one on which, when you've made the decision, you're not sure it's right. I don't think that all decisions that are made in this area or any area fall into the close question category.

The phrase I noted was "arguable." That is a criterion that has been used in one statute or another. It is used in judicial construction of various statutes. Some that come to mind are the labor laws and the antitrust laws. There are lots of situations in which a judgment is made to follow a certain procedure when a question is called arguable. There are probably lots of other phrases. So it seems to me that the case for releasing data without notice, when a *bona fide* trade secret claim has been made or could be anticipated, just hasn't been made.

Finally Mr. Hutt says, "If you don't like the way these regulations are framed, go to court," because the FDA has pledged not to oppose reviewability. Putting aside the question whether the FDA's policy is going to control even the Justice Department in asserting defenses, much less whether it will control the courts,[20] it seems to me that an argument can be made that at least on this question of notice to the trade secret holder, the regulations don't present a reviewable and ripe issue because they are so vague. Mr. Hutt says that he can't figure out a better description of the criteria to apply. Well, if that's the case, how are we to expect a court to decide entirely in the abstract whether, in a concrete situation, legitimate private rights are going to be protected? It seems to me a very good case could be made for the court refusing to hear the issue and saying, "Come back when the FDA has given out or is about to give out your data so we can see what a close question is, and we can see whether, as applied, these criteria meet the requirements of due process."

So without suggesting that the Agency hasn't manfully grappled with the problem up to this point, I think it's fair to ask that it go back and try to refine this whole procedure of notice to the trade secret holder and not simply say, "Well, we have a general policy here; and if you don't like it, take it to court."

Mr. Hutt: I would be happy to take the word "arguable" in lieu of the phrase "close question" because I see absolutely no distinction. If it's a close question, it is arguable. If it is arguable, it is a close question. But if you are saying that notice is required if anyone in the United States could argue with you about it, then I would not accept that because the very things that Mr. Hoffman, is his wisdom, would say are clearly open-and-shut cases, we have had people argue with us about.

Mr. O'Keefe: I have a question addressed to Peter Hutt. Will you release any legal memoranda supporting or explaining your interpretation of a trade secret as well as references mentioned in those memoranda?

Mr. Hutt: The only legal memoranda that exist are right in the preamble. We thought there was no point in preparing additional legal memoranda since, in my view, the public is entitled to know what the legal basis is for what we are doing. I am not aware of any

[20] See *Bradley v. Weinberger,* CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,978, 483 F. 2d 410 (CA-1 1973).

other legal memoranda other than in the preamble, and we will certainly do the same thing in the final order that comes out.

Mr. O'Keefe: Present FDA policy prohibits the release of drafts of new regulations to anyone outside the Agency prior to publication in the *Federal Register*. This policy would appear to be inconsistent with at least the spirit of the FOI regulations. Will the policy be reviewed in the light of the new FOI regulations?

Mr. Hutt: The answer is that it is completely consistent with the policy of the FOI regulations. We say that we will not release internal information that would disrupt our ordinary business. And on the other hand, when we release anything, it will be available to everyone. So our current policy is that we do not release drafts of regulations to anyone until we are prepared to release them to everyone. In that case, we put a notice in the *Federal Register* as we did with the shellfish good manufacturing practice regulations, the Part 90 and cosmetic ingredient draft final orders. That policy will continue, and it will be embodied in the new procedural regulations.

Mr. O'Keefe: Will information given voluntarily to the FDA during an inspecion which is marked "confidenial" be held in confidence? Will the FDA respect such marking with regard to the FOI Act?

Mr. Hutt: Clearly, no. And the regulations spell that out in detail.

Mr. O'Keefe: Is it legal to have these regulations implemented in advance of the finalization period?

Mr. Hutt: Again, the answer is that the statute has existed since 1967. Failure to release the documents would be illegal.

Mr. O'Keefe: What is the rationale for making available to the public food additive petitions that have not been accepted for publication because they would be found to be deficient?

Mr. Hutt: We provide, in the section on information that is submitted voluntarily to the government, that all safety and similar information will be released. It was our feeling that if a petition was submitted, it should be handled on the same basis, as of the moment of filing or rejection for filing. Any information of a safety nature voluntarily submitted would be released.

Mr. Hoffman: This relates to the question of intervention in actions to compel release of information. The statute is an absolute

statute. It may be intended to protect a private right but it creates a public duty on the employee. And I would like to hear Mr. Hutt or someone explain how Mr. Brandenburg, for example, is to be protected from prosecution for disclosing a trade secret simply because the company involved didn't get the word, couldn't afford to come in or didn't realize what was happening to it. The thought did go through my mind that maybe we rely on the good sense of prosecutors, just as company executives do under *Dotterweich*,[21] but there's got to be a better answer than that.

Mr. Hutt: The answer is the regulations. That is one good reason why you have regulations to spell out what, in our opinion, is and is not a trade secret. In our view, if our employee follows the guidelines in the regulation, there is no possibility of prosecution because we point out what is and is not a trade secret. I would like to distinguish between the FDA regulations and the regulations of virtually every other agency. And I think that, if you read the other agency regulations, you would agree with this.

Most other agencies, including the Department of Health, Education and Welfare (HEW), simply quote the statutory language. They do not define what a trade secret is, much less have something equivalent to our lengthy regulations on the types of records we will release in NDAs, food additive petitions, color additive petitions, and whatever. We are the only agency in the entire Federal government of which I am aware that has categorized our documents and said what we will and will not release. That is why, incidentally, I disagree with Mr. Hutt on the question of reviewability.

If we had merely quoted the statutory language, I would agree with him. We did not. We set out what documents you get and what documents you do not get. It appears to me that this is absolutely ripe for judicial review at this time. Similarly, since we have gone to that degree of specificity, unless those regulations are challenged by the industry and overturned, it is my opinion that any FDA employee can safely operate within them without fear of criminal prosecution.

Mr. O'Keefe: Will the FDA require the source of the information to defend a court challenge if the Agency has accepted the data under challenge as confidential in a presubmission review?

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[21] *United States v. Dotterweich*, 320 U. S. 277, 285 (1943).

Mr. Hutt: Yes. We would operate under the section in which we require the person who submitted the records to justify their confidentiality, or he has waived his rights to trade secret status.

Mr. O'Keefe: Mr. Brandenburg has stated that over 3,100 FOI requests have been received and processed during 1974 and the first half of 1975. Is there a publicly available list or log on these requests giving reference to: one, the name of the requesting party; two, general reference to subject matter requested; and three, disposition of that request? If so, how do you get access to that log?

Mr. Brandenburg: We have not made a log of requests during that period. We are now maintaining a log which we started approximately a month and a half ago and keep on a daily basis. Anyone can obtain a copy of it, including the FOI service that was mentioned before.

All requests will be logged in, whether received by and responded to by our field districts or not. Sooner or later those requests are received in the Public Records and Documents Center. They're entered into our log and the file is maintained.

Mr. O'Keefe: Assuming that a regulated company wants to be completely apprised as to how the FDA views the company insofar as plant inspections and safety matters are concerned and insofar as the labeling of its product is concerned, what documents can that company request and receive from the FDA under the FOI regulations? In other words, what specific documents in the FDA's possession are available to a company that wants to know how it stands with the Agency *vis-a-vis* its labeling and manufacturing practices?

Mr. Brandenburg: All documents, except internal memoranda and comments which reflect opinion on the part of, let us assume, an inspector, are available. Of course, communications between the client and the attorney are also considered to be exempt from disclosure. Even internal documents which concern the firm are, in some cases, released at the Commissioner's discretion. And we are considering when the Commissioner needs to exercise that discretion, he usually does so in the interest of furnishing more information.

Mr. O'Keefe: Experience indicates the hearing clerk office has given anyone anything upon request. To what extent will the Public Records and Documents Center under the press of business permit its nonpolicy officers below management level to decide upon disclosure requests?

Mr. Brandenburg: We have two questions there; rather, one observation and one question. The observation that the hearing clerk will give anything to anybody upon request is entirely correct and that's what we intend. Nothing is on file in the hearing clerk's office that should not be divulged to the public and is not publicly available.

The Public Records and Documents Center, that portion of it which deals with the FOI Act, is a different matter. On file there are a number of documents including our manuals which have been reviewed by professionals and are in a shape to be completely divulged. When we receive a request for part of that manual or a whole manual, the clerical personnel can fill that request because these have already been purged of information (I use that word reluctantly), purged of information that is not, according to our regulations and the law, releasable to the public. Other than that, clerical personnel do not participate in the decision to release or not release a record. That is done by the component FOI officers or the acting FOI officers all of whom are professional personnel.

Mr. O'Keefe: If someone has requested information concerning company data from you and that company finds out in some way or other that the information has been requested and they think it is a close question, would you accept a telephone call and accept that decision in that instance?

Mr. Brandenburg: Yes, we would do that. And as a matter of fact, when we do have questions about requests that we think need clarification or where we believe that the person making that request really doesn't mean what he said, we have been calling them. In most cases, we use a telephone.

Mr. O'Keefe: Do I interpret that correctly? In other words, if I am a member of company X's staff and I have a question or I find out that you're contemplating releasing some information, the only thing I have to do in order to trigger the consultation provisions is to call you to notify you that I think there is a close question. Let us assume in that instance that you do not think there is a close question.

Mr. Hutt: No. The fact that someone thinks there is a close question is not enough. As I say, we have had people tell us that, even though they have previously made public their formula, they still do not think that we ought to release it. Now that is not a close question, but they argue it. And we will not be guided by their determination.

Mr. O'Keefe: What risk does the FDA incur by disclosing data which a court may later declare to be a trade secret not properly disclosable?

Mr. Hoffman: If a court should find the document was not disclosable, and it were in a grievous case, there presumably would be a criminal prosecution, or at least it would be considered.

Mr. O'Keefe: How much information in a discontinued Investigational New Drug (IND) file will be released?

Mr. Brandenburg: A discontinued IND is not necessarily an IND that has been abandoned, and I think we need to know the circumstances before we could say how much would be released. It may be that an IND would be discontinued for many reasons other than abandonment.

Mr. Hutt: I think that was discussed in the preamble at some length. I am not sure we could say any more than what we said there. If, for example, someone starts out with clinical studies on an IND, gets an adverse animal result, stops the clinical studies to pursue the animal testing in order to see whether that can be resolved with the thought that the IND will be instituted as soon as possible, we have already, in a specific instance, said that is clearly not abandonment of the IND.

Mr. O'Keefe: What is the status of safety data being developed for a possible New Animal Drug Application (NADA) for a drug formally regarded as not a new drug? Is this information confidential?

Mr. Hutt: If it is submitted in a NADA, it is confidential unless we conclude that it is an old drug, in which case it is no longer confidential.

Mr. O'Keefe: Must a specific request be made to mark it "confidential"?

Mr. Hutt: Clearly, no. The regulations say marking things "confidential" has no impact or value whatever.

Mr. O'Keefe: Do FOI requests made to regional offices appear on the public log in Washington?

Mr. Brandenburg: Yes, they do.

Mr. O'Keefe: FD-2275's contain names of company officials. Further, the fact that an inspection is pending regarding a NDA discloses the

names of raw materials. Would that kind of information be deleted from disclosure?

Mr. Hutt: That is hard to answer as a general proposition. We would have to look at all the facts on a specific case to see whether it is a trade secret or not. If it was something like we used to have, where the issue was whether the person had authority to use methadone and there were between 500 and 1,000 applications, that is hardly a trade secret. If it were a unique drug and it did not disclose something ahead of time, we would then regard it as a trade secret.

Mr. O'Keefe: Would the fact that a NDA has been turned down be released? Would the data contained in the NDA be released at that time?

Mr. Hutt: Again, it depends on what kind of a turn-down it is. If it is a final, total, conclusive turn-down on the ground that it is unsafe or ineffective and no further data could possibly resolve the issue, the answer is yes. If it's a turn-down in the sense that we turn down most applications at one point or another leading toward the development of further data and further negotiations, the answer is no. That would not be released.

Mr. O'Keefe: Is an FDA log kept and available on denials of requests for information?

Mr. Brandenburg: Those are entered into the log as it appears . . . . all denials.

Mr. Hoffman: May I follow up that question with one that really hasn't come up? Mr. Hutt referred to the Department of Justice FOI Committee. I've wondered what procedural mechanism there is for consulting that Committee in the event of a decision to deny.

Mr. Hutt: The FOI Committee in the Department of Justice recently had to change its rules. They were getting inundated with so many requests for consultation from the agencies that they could not keep up with them. As a result, on an initial denial, they will not accept a routine consultation at this time. Only at the point where an agency is threatened with litigation would they get into it. Obviously, that is flexible. If it's an important new issue never before considered, I am sure that they would discuss it. There is no formal procedure that I am aware of, but they do have a regulation.

Mr. O'Keefe: With regard to disclosure of information contained in, for example, master files filed with the FDA by basic manufacturers not

identified with an IND or a NDA, who at the Agency determines the validity of the applicant's need for data contained in the master file and under what criteria?

Mr. Brandenburg: No one. The master file is treated as any other submission. And the divulgence of material from it proceeds in accordance with our regulations.

Mr. Hutt: In other words, the critical thing is that no one must show a need to see any document in FDA files in order to see them.

Mr. O'Keefe: Will you answer a few of the written questions?

Mr. Hutt: A publicly held company discharging its SEC obligations issues a public statement correcting an incorrect rumor regarding a hitherto undisclosed product under IND or NDA. Does this action result in releasing the FDA from its confidential position concerning that product?

Yes, to the limited extent provided in the regulations. There are four or five questions here which show that this is not well understood. All that we have said is that once the company acknowledges or in some other way discloses the existence of an IND, we will no longer pretend that the IND does not exist. That does not mean that we release anything in it. The only thing that we can do, the only impact we will have, is under Section 314.14(d) which says the Commissioner may, at his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue; for example, at an open session of an FDA advisory committee or pursuant to an exchange of important regulatory information with a foreign government. This does not say that we would release any of the safety or effectiveness information, or the formula, or manufacturing information, or anything else in that IND. But we did conclude that if a company says it has an IND and it's in the Pink Sheet and it has been on the de Hahn list for five years, for the FDA to say, "We cannot confirm that there is an IND," is utterly ludicrous.

If a request for data collected by the FDA in support of a proposed regulation is answered by a certificate of nonexistence, is the initial request a continuing one carrying a burden on the Agency to provide any future data collected?

Absolutely no. That is true across the board. We've had, for example, the legal department of a company write in to say that, since they had trouble getting the 2275 from their own company of-

ficials, would we mind sending it to them. We said there was no way we would agree to do that. They would have to ask for specific ones at a specific time. That's an actual case.

Here is a question about notice. Have you considered the constitutional question of due process?

The answer is not in the FOI Act because notice is not covered. What the question is asking is whether the failure of the FOI to include a notice provision makes the FOI unconstitutional on due process grounds. My conclusion is no, and we did consider that.

Can HEW regulations on adverse Agency publicity be reconciled with a disclosure of damaging corporate information known by the FDA to have damaging impact without any notification to the firm?

The answer is squarely yes. If you go back to the recommendation of the Administrative Conference of the United States on adverse publicity, it flatly exempts from its recommendation any information released under the FOI Act. And that was a conscious decision both by the person who wrote the report and recommendation and by the Administrative Conference.

If a NDA is withdrawn as a result of an over-the-counter monograph being written, what is the status of the trade secret information contained in the withdrawn NDA? Will such items as raw clinical data, full reports of clinical trials, manufacturing, and control information be declared public?

Raw clinical data, yes. Full reports of clinical trials, yes. Manufacturing and control information, no.

There are several questions dealing with the Section 314.14(d) issue of release of information based upon the disclosure of the existence of an IND.

Again, I emphasize the only thing that we do is acknowledge that the IND exists. And under the limited circumstances set out in paragraph (d) of Section 314.14, we can disclose summaries. But we would not do it uniformly. We would not do it upon public request.

Is an IND or NDA considered to be voluntarily submitted?

No, it is not, nor is a food or color additive petition, because they are submitted, obviously, to obtain governmental action that is required before a product may be marketed.

When will an inflation impact statement be filed on the regulations, particularly as to their loss or potential loss of competitive advantage for innovative research?

The entire subject of inflation impact statements is subject to regulations that are currently being drafted by HEW pursuant to the OMB guidelines and the President's Executive Order that was issued sometime ago. Frankly, at this stage of the game, there is nothing that any of us here could tell you until those become known and we have some guidelines to go on. I would say, however, that including this concept within inflation impact is stretching things beyond all recognition. I could say there is little or no possibility that the idea of potential loss in competitive advantage under FOI will ever be the subject of any inflationary impact statement.

Now here is a question I have a little bit of difficulty in understanding. Does section 314.14(g) restrict the application of Section 314.14(f) with respect to availability of manufacturing methods, formulas, etc. contained in NDAs which are abandoned or withdrawn?

Where an IND or NDA is abandoned or withdrawn, the safety and effectiveness information would, with rare exceptions, be provided. We would probably have to take a closer look as to whether the manufacturing data and information would still have trade secret value in terms of other products made by the same manufacturer. So there is some comparability and also some distinction. The one thing I would emphasize is that one must look, in issues of this kind, at the specific facts.

The amendments extend venue on suits requesting disclosure to include plaintiff's district. The FDA denials would, therefore, be litigated in any district court. If disclosure were contested by a submitter—that would be pursuant to 4.45—could the submitter sue in his own district and would the FDA waive venue?

The answer is the FDA would not waive venue and the suit would have to be brought with proper venue. We would not waive venue.

To what extent will the FDA use 18 U. S. C. 1905 to prosecute Agency document leaks?

We have already answered that, but I want to clarify one thing. We will clearly prosecute any leaks involving material that is covered by section 301(j) of the Federal Food, Drug and Cosmetic Act. Now

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there is a nice legal issue as to whether 18 U. S. C. 1905 is procedural or substantive in nature. There are two district court decisions holding squarely that 18 U. S. C. 1905 has no substance whatever. It is not a prohibition against release by any government agency of confidential commercial information. It is merely procedural in nature, and says that if there is another statute which prohibits such disclosure, then that other statute is to be backed up by 18 U. S. C. 1905 providing criminal penalties. There is no court that has held to the contrary.

Is an FDA inspector authorized to sign any document which would prevent public disclosure of information voluntarily submitted to an advisory panel or to anybody else under any circumstances?

The answer is flatly no. I recently had the question put to me by our field force as to whether the inspector could sign a statement in receipt of documents at a factory which says that it is the position of the company that this is trade secret information. And I have said, "No, he cannot sign that because that could be misinterpreted as an FDA agreement with that position." If a company wants to submit information and a separate letter, not signed by the inspector, stating its opinion that this is confidential, that is fine with me. But we cannot sign a receipt that indicates that we might agree with that determination.

Will the FDA in the future submit information prohibited from disclosure outside the department under Section 301(j) to Congress? The question says that FDA has done so in the past.

I cannot guarantee everything we have done in the past. In the future we cannot do so, and the regulations state that.

Will public, student or family tours through a manufacturing facility result in this being classified as public disclosure of manufacturing processes? No.

Will permission to allow a university class, studying quality assurance, to witness actual plant operations be public disclosure of information given to the university class?

The answer is yes, it will be. This reminds me of a situation in which we received a request for certain information, asked the company if they had ever released it or would release it, and they said no. It was formula information. We said all right, we will not release it. On appeal, an enterprising physician in the office of the secretary called the medical director of the company, asked for the information,

and was given it over the phone. He did not say he was from the government. We immediately released the information to anybody who wanted it, and will do so in the future. And we did not tell the company and give them a chance to explain nor would we in the future. People cannot be inconsistent. If you're going to release something to a physician or to a university class or whatever, that is public disclosure. And I think our regulations are about as clear as they can be on that point.

Mr. Hoffman: How would you treat unauthorized disclosures by company personnel without the authority to do it?

Mr. Hutt: What we have said is if it is a lawful disclosure, it is a disclosure. If he is an agent of the company and is not violating a law or a contract or anything of that nature, then that is a lawful disclosure. We have the same problem in the FDA. Every organization has the same problem. Otherwise you would have companies put out internal directives saying nobody should release anything they should not release. And they can not hide behind that.

After submitting a NDA, will the FDA entertain a request that asks the Agency to indicate what information the FDA considers confidential?

No, we will not. The reason we will not is because that is a determination that can be made only at a particular point in time. And to do that before there is any request for it seems utterly without any purpose at all.

Could there be a difference of opinion so that, without this request, the manufacturer might never know what specifics will be considered confidential?

Again, the kind of information we would give out without telling the company would be reprints from medical literature and things that have clearly been made public. On any close issue, we would discuss it with the company to find out, for example, whether information has or has not been publicly disclosed.

How can a manufacturer protect the confidentiality of "confidential commercial information" which, together with nonconfidential information, has been submitted to an FDA advisory committee and which is the subject of a presentation to the committee in an open session?

The answer is that information given in open session is disclosed to the public because an open session includes all members of the

public and any transcript of an open session is freely available to anybody at anytime. Indeed, under our current guidelines, any member of the public can attend any open session of an FDA advisory committee meeting and make his own transcript with his own tape recorder.

Have you personally reviewed the public log now being used to notify the public of FOI requests? Do you feel this public log is sufficient notice either to companies who have their employees review it by going to the FDA in Rockville or via the new FOI services, commercial service, in view of the apparent fact that the public log includes many handwritten general entries, such as "data on NDA acts" or "data on contraceptive drugs"?

There is a limit as to what the FDA can do. The answer to this question is that I think the log is quite adequate. If anyone wants to look behind the log entry, you can request an opportunity to review the request itself, namely, the letter that stands behind it. Therefore, it would be of no use to, in effect, take the letter and reproduce it in the log itself. Besides with this marvelous new commercial venture, there's no reason for us to worry about it.

In listing records requested in the FDA's public log of FOI requests, do you have uniformity as to naming of firms or other specificity of the record?

We try. But we are not going to be as specific as the request itself and we will generally just name the firm or other type of identification in the way that it comes in the letter.

Are safety and effectiveness data on NADAs trade secrets? If they are, why does the EPA contend such data are not trade secrets when related to pesticides?

The answer is very easy. There is a difference in the statute. There is a purposeful change under the new Pesticide Act which says that such information can be released and will be paid for by the person to whom it is released. Until the Federal Food, Drug and Cosmetic Act is changed to do that, we are going to keep doing it the way we are.

How will the FDA determine when trade secrets or confidential information become available based on a product being discontinued?

What we will have to do is base that upon the information available in our IND and NDA files. If there is any question, we will get in touch with the company.

How can the FDA determine when information has already been provided to another person? This involves the whole issue of when does the FDA know when something has been previously disclosed to the public?

That's the very issue that our FOI officers have had the most difficulty with. We presume, unless we have information to the contrary or any reason to believe to the contrary, that the information has not been disclosed to the public and we will act on that basis. If there is any reason for believing the contrary, we will get in touch with the company and ask for some kind of certification. That kind of certification would be subject to the provisions of the false reports to the government act, 18 U. S. C. 1001. Thus, if a company official certified that, to the best of his knowledge and belief, it has not been made available to the public and that is not correct and he had reason to believe it was not correct, that would be a criminal felony offense.

With respect to production formulation data for food additive petitions, what assurances will the Agency give that such data will not be released inadvertently or deliberately?

The only assurance I can give you is the criminal penalty. And we have enforced the criminal penalties in Section 301(j) where people have deliberately released information. In terms of inadvertence, all I can say is I am not aware of such information having been inadvertently released. We would probably, as in all questions of criminal liability, look at the facts and determine whether prosecution is warranted.

Finally, a very lengthy question which winds up, how can I protect my valuable trade secret in this instance? The problem arises when someone has a new idea and in order to try to be helpful to the FDA and also to try to prevent the FDA from starting any seizure or other actions, he wants to give the Agency the information on a voluntary basis.

In our experience, in most instances, data of that kind are given to us voluntarily because the company wants to protect itself. It is not a public interest type of gesture. It is because the company has its own best interests at heart. That information will not be protected. That is information given voluntarily. It relates to safety and effectiveness, and it will be released. The alternative, if you do not want it to be released, is not to give it to us and risk the possibility that we will look at the product and seize it.

Mr. O'Keefe: Thank you, Peter. Thank you all very much for participating in this briefing session. **[The End]**

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