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FDA's Freedom Of Information (FoI) REGS

WHOLE NEW BALLGAME FOR DRUG-COSMETIC-DEVICE-DIAGNOSTICS industries in relationships with FDA, competitors, consumerists & others as result of promulgation by Com. Schmidt of *Freedom-of-Information (FoI)* regs for early publication in *Federal Register*.

Full text of *FoI* regs provided on pages S-1 through S-30, white paper. Provisions could, in time, have more profound influence on day-to-day relationships between the regulated & the regulators than enactment of a major new statute.

FDA IS GOING TO OPERATE IN A GOLDFISH BOWL, and everyone who comes in contact with FDA will have to jump into the same bowl – like it or not. When you write a letter to FDA, or make a telephone call, better think how you would come out if contents of letter - or FDA memo on phone call – showed up in the Washington-Merry-Go-Round column.

PHARMACEUTICAL BOARD CHAIRMAN & OTHER EXECS may have to be more close-mouthed with financial analysts on INDs & NDAs – disclosures can trigger FDA release of other info. *REASON:* Crucial element in FDA's decision on whether to treat the very existence of an IND and/or NDA file as a non-disclosable *secret* depends on whether the company or other sponsor keeps the *secret*. In short, if a company reveals the *secret*, it can trigger additional disclosures by FDA. After *approvable* letter issued, FDA discloses summary of data from NDA; all correspondence ..... Page A-2

COSMETIC PRODUCT EXPERIENCE REPORTS TO FDA protect names of brands and the mfrs. making voluntary disclosure by *Freedom of Information (FoI)* regs. A somewhat different situation is presented by the cosmetic ingredient and raw material composition voluntary reporting system which also was developed by the Cosmetic, Toiletry & Fragrance Assn. (CTF) in response to FDA declarations of a need. The new *FoI* regs do not include a blanket, across-the-board provision – similar to the one covering product experience reporting – that takes care of the confidentiality problem with regard to reporting ingredients and raw material composition ..... Page A-3

DEVICE & DIAGNOSTIC PRODUCT DATA VOLUNTARILY FILED WITH FDA subject to *FoI* regs. There is no specific provision in the *FoI* regs covering data on medical devices and diagnostics. In fact, they are mentioned only several times in the lengthy preamble – somewhat in a passing way.. Page A-4

THREE KEY DEFINITIONS IN THE *FoI* REGS ARE: (a) Trade Secrets; (2) Confidential commercial or financial information; and (3) *Information previously disclosed to the public.* Long term effect of regs could be to increase FDA paper flow, dry up personal communications. "Peter's preamble" covers everything, and concludes an invitation to outsiders who disagree to "institute legal action in the courts." Selected quotes from the preamble. Schmidt aside to Kennedy: Unafraid to surface internal memos on controversies; way of science. Page A-5

PLAINTIFF'S EXHIBIT
WCD-181

PHARMACEUTICAL BOARD CHAIRMEN & OTHER EXECS MAY HAVE TO BE MORE CLOSE-MOUTHED WITH FINANCIAL ANALYSTS ON INDs & NDAs: DISCLOSURES CAN TRIGGER FDA RELEASE OF OTHER INFO

Pharmaceutical industry board chairmen, presidents and financial VPs probably will be more close-mouthed from now on in talking with financial analysts and others about new products in the Investigational New Drug (IND) or New Drug Application (NDA) stages of R&D as a result of FDA's newly promulgated ***Freedom of Information (FoI)*** regs.

Ironically, the *FoI* regs, designed to make FDA the most open agency in all govt. – and its records the most readily available for public disclosure -- could result in shutting off the flow of information on research program results and R&D activities from pharmaceutical companies to the public, to the scientific community generally, and to shareholders and financial analysts.

> *REASON:* **Crucial element in FDA's decision on whether to treat the very existence of an IND and/or NDA file as a non-disclosable *secret* depends on whether the company or other sponsor keeps the *secret*. In short, if a company reveals the *secret*, it can trigger additional disclosures by FDA.**

Once the *secret* is out – the existence of an NDA file has been "publicly disclosed or acknowledged" by the company or sponsor – the FDA commissioner "may, in 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, e.g., at an open session of an FDA advisory cmte."

Publicly disclosed or acknowledged, a phrase of art appearing frequently in the *FoI* regs, is explained in the bible-dimension, 233-typescript-page *Peter's Preamble* that explains administrative determinations, FDA commissioner decisions, and even provides learned judicial pronouncements on legal issues.

After *Approvable* Letter Issues, FDA Discloses Summary Of Data From NDA; All Correspondence

After FDA has issued an NDA *approvable* letter, the existence of the NDA will be disclosed by FDA by placing it on a list of *approvables* maintained by BuDrugs for public inspection. Also, "unless *extraordinary circumstances* are shown," the following data and information from the NDA file are made immediately available for public disclosure:

❶ "A summary or summaries of the safety and effectiveness data and information submitted with, or incorporated by reference, in the NDA file." The summaries do not constitute the full reports on the investigations on which the NDA was cleared.

For NDAs cleared before July 1, 1975 – starting with the beginning of NDA time – summaries will be prepared from FDA internal documents, with the following deletions: Names and identities of patients, test subjects or investigators; and "any inappropriate gratuitous comments unnecessary to an objective analysis of the data."

The summaries to be disclosed for NDAs cleared after July 1, 1975 will be prepared either by BuDrugs or by the sponsor of the NDA, as required by BuDrugs and reviewed by it before release.

❷ "A protocol for a test study," unless it can be demonstrated that such protocol is protected under the definition of *trade secrets* or *confidential commercial information.*

❸ "Adverse reaction reports, product experience reports, consumer complaints" and similar data after deletion of identifying names to protect the privacy of individuals who used the product.

❹ "A list of all active ingredients and any inactive ingredients" that might have been previously disclosed by the sponsor.

❽ "An assay method or other analytical method, unless it serves no regulatory or compliance purpose" and can be shown to fall inside the *trade secrets* or *confidential commercial information* categories.

❾ "All correspondence and written summaries of oral discussions relating to the NDA file" with secrets deleted. Other parts of the regs detail how records of oral discussions are to be kept and ground rules for disclosure of correspondence.

FDA will not disclose the following data from an NDA file, even after the *approvable* letter, unless the information has previously been made public by the company or sponsor:

❿ "Manufacturing methods or processes, including quality control procedures."

⓫ "Quantitative or semiquantitative formulas."

⓬ "Production, sales, distribution and similar data and information" except in FDA compilations that do not reveal individual secrets.

FDA will disclose all safety and effectiveness data in an NDA file when: (1) The NDA has been abandoned; (2) A final determination is made that the NDA is not approvable; (3) Approval is withdrawn and all legal appeals have been exhausted; (4) FDA determines that the drug is not a *New Drug*; and (5) FDA decides the drug can be marketed without submission of data.

EDITORS' NOTE: *See Part 312, INDs, starting at bottom of page B-24 (white), and Part 314, NDAs, starting on page B-25 (white), in text of* FoI *for details. Certifiable antibiotics, New Animal Drug Applications (NADA), and new biological products are subject to similar procedures, outlined in separate sections of the* FoI *regs.*

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NAMES OF BRANDS & THE MFRS. MAKING VOLUNTARY COSMETIC PRODUCT EXPERIENCE REPORTS TO FDA PROTECTED FROM DISCLOSURE BY FREEDOM OF INFORMATION REGS; INGREDIENT REG DIFFERENT

Cosmetic mfrs. and marketers complying with the FDA/CTF *voluntary* program for filing *product experience* data with the govt. apparently are protected against disclosure of brand names – and their own names – by across-the-board Section 4.111 of the *Freedom of Information (FoI)* regs (see page B-18, white).

> **When submitted voluntarily by a mfr., *"adverse reaction reports, product experience reports, consumer complaints and other similar data,"* under Section 4.111 (3)(ii)(c) of the *FoI* regs, will be disclosed to the public only after deletion of *"names and any other information that would identify the mfr., or the brand designation of the product."***

The *FoI* regs state, however, that FDA can disclose the type of product, or its ingredients, in connection with the release of product experience data voluntarily submitted by mfrs. Apparently this refers to the kind of composite cosmetic product experience figures disclosed in the tabulation presented by FDA Cosmetic Technology Div. Deputy Director John Wenninger at the Dec. 3-4 Food & Drug Law Institute meeting in Washington. Included in the tabulation was a column showing the number of product experiences reported per million units of products distributed, broken down into major categories.

A somewhat different situation is presented by the cosmetic ingredient and raw material composition voluntary reporting system which also was developed by the Cosmetic, Toiletry & Fragrance Ass. (CTF) in response to FDA declarations of a need. The new *FoI* regs do not include a blanket,

across-the-board provision – similar to the one covering product experience reporting – that takes care of the confidentiality problem with regard to reporting ingredients and raw material composition.

When FDA promulgated the voluntary ingredient reporting reg, it included a provision that the mfr. reporting on a cosmetic product or on a raw material could mark the Report Form "confidential." A procedure was set up so that this would automatically trigger a review by FDA of the confidentiality claim, and if it was denied, the mfr. could appeal.

The new *FoI* regs regard all trade information voluntarily filed with FDA as available for disclosure, unless protected by the definitions of trade secrets or confidential commerical information. The regs have no special protection for information voluntarily filed in the past under special programs, and they reject the concept that use of the word "confidential" on any document gives it any special status.

A special procedure for "presubmission review of request for confidentiality of voluntarily submitted data" is provided in the new *FoI* regs (see Section 4.44, page B-8, white). Permission is granted to withdraw the material, if the "presubmission review" decision is unfavorable.

To "deal fairly" with cosmetic mfrs. that have already submitted ingredient disclosures, accompanied with confidentiality claims, preamble to the *FoI* regs says these filings, if not already resolved, will be handled via the new presubmission procedure. If the mfr. who made the filing doesn't like the decision on confidentiality, the ingredient disclosure data can be withdrawn.

With the advent of FDA's regs requiring mandatory label disclosure of cosmetic ingredients, issued under the Fair Packaging & Labeling Law, the voluntary filing program is not so important with regards to finished cosmetic products, but it still may be significant in relationship to composition of raw materials.

Confidentiality of data filed with FDA in color additive petitions is covered in a special section in the *FoI* regs, Part 8, Section 8.9 (see page B-20, white). The criteria for determining whether color additive data submitted to FDA should be disclosed are close to those established for drugs, antibiotics, and other areas covered by various forms of licensing.

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DEVICE & DIAGNOSTIC PRODUCT DATA VOLUNTARILY FILED WITH FDA SUBJECT TO FoI REGS

Large amounts of data have been submitted by mfrs. of devices and *in vitro* diagnostics to FDA during the past several years on a voluntary basis, chiefly in connection with the classification and standards programs undertaken with the help of outside advisory cmtes.

Specific product data undoubtedly was provided in many instances on the basis of informal agreements, spoken understandings, and a general spirit of industry-govt. get-togetherness. The data already in FDA files are now governed by the *FoI* regs as to disclosure on confidentiality status, regardless of the circumstances under which it was supplied.

There is no specific provision in the *FoI* regs covering data on medical devices and diagnostics. In fact, they are mentioned only several times in the lengthy preamble -- somewhat in a passing way.

Nevertheless, the general provisions in the *FoI* regs covering data submitted voluntarily to FDA and determination of confidentiality are applicable to devices and diagnostics. When a new law is passed, devices and diagnostics will still be subject to *FoI*, but the legal base will shift from voluntary to mandatory.

KEY TO FoI REGS: PREVIOUS DISCLOSURE OF INFORMATION NEGATES ANY CLAIM TO PROTECTION AS TRADE SECRETS OR CONFIDENTIAL COMMERICAL INFORMATION; FDA & INDUSTRY INTO NEW ERA

The three key definitions in the *FoI* regs are: (1) Trade secrets; (2) Confidential commercial or financial information; and (3) *Information previously disclosed to the public.* Prior disclosure of information is the most important – from industry's standpoint -- because it negates trade secrets or confidentiality status which would otherwise protect data or information submitted to FDA from becoming part of the agency's open file. Say the *FoI* regs:

- **"Any FDA record that is otherwise exempt from public disclosure. . .is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy." (See Section 4.81, p. B-12, white, text of *FoI* regs.)**

- A trade secret, according to the regs, "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(a), p. B-10, white).

- "Commercial or financial information that is privileged or confidential," the regs say, "means 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(b), p. B-10, white).

Long-Term Effect Of Regs Could Be To Increase FDA Paper Flow, Dry Up Personal Communications

Effective date for the *FoI* regs is 30 days after publication in the *Federal Register*, expected in the near future, which would put them into operation sometime in mid-Jan. However, because of the length of the regs and their preamble, written comments or criticisms will be accepted up to 60 days after publication in the *Federal Register.*

- There should be very little hope that any written comments submitted in the next 60 days will produce a significant change in even one paragraph or one sentence of the regs. FDA said the comments should be limited to areas and points not covered in extensive filings made on the original May 1972 proposal, or in the massive preamble to the new regs.

Designed to make FDA the most open agency in govt., and hailed as a model for generating a massive new flow of information, the *FoI* regs, ironically, conceivably could cut down the movement of information in two key areas:

(1) From pharmaceutical board chairmen to security analysts, investors, the public, and science generally because of the fear that inadvertent disclosures would adversely affect the status of important information in FDA files; and (2) From FDA's very important mid-level execs who might clam up in discussions with industry and outside scientists in the face of the prospect that all correspondence and inside memos on telephone calls, et al, will be released when an NDA is approved.

FDA Com. Schmidt, in announcing to a Dec. 3 Food and Drug Law Institute banquet that he had just signed the regs, hailed them as the "most extensive and specific" ever published by any govt. agency. The regs, he added, "will stand as a monument to Peter Hutt's superb draftsmanship." Schmidt also praised the way FDA bureau heads and staff, plus its Policy Board, had worked

on the lengthy text. The "Peter's Preamble" to the regs runs 233 typescript pages, and covers everything, concluding with an invitation to outsiders who disagree to "institute legal action in the courts." Selected quotes from the preamble:

● "The criteria for a trade secret and for confidential commercial information are substantially different. The former depends entirely upon the competitive advantage attributable to the specific information involved, whereas the latter may be applicable even if there is no specific competitive advantage involved, if such information is generally held in strict confidence according to usual industry practice. In both instances, of course, lawful prior public release of the information automatically destroys the confidential status of the information."

● "Use of an ingredient by more than one mfr. for the same purpose is not, in itself, sufficient to justify a conclusion that such use is not a trade secret. The commissioner recognizes that whether the use of an ingredient constitutes a trade secret will depend upon a number of factors, and primarily whether it has previously been disclosed to the public. . .

● "A representation by a company that, to the best of its knowledge and belief, the ingredient has not previously been disclosed to any member of the public, will be sufficient to create a prima facie case of confidentiality, which may be rebutted by FDA, if it determines that the ingredient has in fact become public knowledge."

● "Any letters to or from a member of Congress, as well as summaries of oral discussions, regardless of whether the member is acting in an official capacity or as a member of a duly authorized cmte., will be available for public disclosure except to the extent that the correspondence contains trade secrets or other nondisclosable information."

Schmidt Aside To Kennedy: Unafraid To Surface Internal Memos On Controversies; Way Of Science

● "FDA has received a number of requests with respect to prior employment experience of present agency employees, and present employment of past agency employees. Although no such lists had been kept in the past, the commissioner concluded that research should be undertaken in order to respond adequately to inquiries of this type."

● "Experience during the past two years has shown that mfrs. and MDs are uniformly unwilling to divulge consumer complaint or adverse reaction information, or other materials of this type, voluntarily except on a pledge of confidentiality."

● "A list of all drugs subject to Investigational New Drug notices constitutes trade secret information that may not be disclosed to the piblic."

● "The commissioner will issue in the near future comprehensive new procedural regs. . . that will include provisions governing all aspects of the activities of the advisory cmtes."

● "Private acknowledgment of the existence of an IND to a consultant is insufficient to constitute public disclosure. Discussion with other scientists who are not paid consultants, however, or with securities analysts, or acknowledging the existence of an IND to any such person, is sufficient to break the confidentiality of the existence of an IND. The commissioner notes that the existence of an IND is often common knowledge within the industry and the scientific world, and that confidentiality of such information is becoming more and more unusual."

● Re disclosure of internal FDA memos showing controversies and reversals of recommendations: "the commissioner believes that such disclosure will not harm the regulatory efforts of the agency, but indeed will serve to foster better public understanding of the internal discussion about scientific and medical issues that must always characterize an open and responsive regulatory agency."

FDA's *Freedom Of Information (FoI)* REGS; FULL TEXT, AS SIGNED BY COM. SCHMIDT

EDITORS' NOTE: *Prepared from a certified, typescript copy, scheduled for* Federal Register *publication in near future. No deletions except for statutory references. Abbreviations are those used regularly by "The Pink Sheet." Screening, occasional paragraphing, graphic makeup devices added.*

See page B-2 for section-by-section index of Part 4 -- Public Information -- the across-the-board regs, with page-number references supplied by the editors. See page B-15 for list of 28 sections and paragraphs in already existing FDA regs which are amended by Part 4; 11 of these are included with amendments in promulgated version of FoI *regs.*

SUBCHAPTER A – GENERAL

PART 1 -- REGULATIONS FOR THE ENFORCEMENT OF THE FD&C ACT & THE FAIR PACKAGING & LABELING ACT

1. In Part 1, by adding a new paragraph (c) to § 1.6 to read as follows:

§ 1.6 Presentation of views under section 305 of the act.

(c) Records relating to this proceeding constitute investigatory records for law enforcement purposes and may include inter- and intra-agency memoranda.

(1) Notwithstanding the rule established in § 4.21 of this chapter, no record relating to a section 305 hearing is available for public disclosure prior to the consideration of criminal prosecution based upon that record being closed, except as provided in § 4.82 of this chapter. The Commissioner will exercise his discretion to disclose records relating to a section 305 hearing pursuant to § 4.82 of this chapter prior to the consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of criminal prosecution is closed, such records are available for public disclosure except to the extent that the exemptions from disclosure in Subpart D of Part 4 of this chapter are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of criminal prosecution based upon a particular section 305 hearing shall be deemed to be closed within the meaning of this section when a final decision has been made not to recommend criminal prosecution to a U.S. attorney based upon that hearing, or such recommendation has been finally refused, or criminal prosecution has been instituted and the matter and all related appeals have been concluded, or the statute of limitations has run.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(5) Names and other information which would identify a FDA employee shall be deleted from section 305 hearing records prior to public disclosure only pursuant to § 4.32 of this chapter.

PART 2 -- ADMINISTRATIVE FUNCTION, PRACTICES, & PROCEDURES

Subpart G -- Public Information

2. In Part 2, by deleting Subpart G -- Public Information containing § 2.115 *Fee schedule for searching, supplying, and certifying records*. Concurrently, the information in this subpart is being recodified into Part 4 as § 4.42.

3. By revising Part 4 to read as follows: