

# C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION  
DEC 21 1999

December 10, 1999

E. EDWARD KAVANAUGH  
P R E S I D E N T

Charles J. Ganley, M.D.  
Director  
Division of OTC Drug Products (HFD-560)  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research  
Food and Drug Administration  
9201 Corporate Boulevard  
Rockville, Maryland 20850

Re: Comments of CTFA on the Exemption Process;  
Final Rule on OTC Drug Labeling; Docket 98N-0337

Dear Dr. Ganley:

As requested, we are providing a written summary of the presentation made by The Cosmetic, Toiletry, and Fragrance Association ("CTFA") to the Food and Drug Administration ("FDA") at the OTC Drug Labeling Working Group Meeting on November 23, 1999 regarding the OTC drug labeling small package exemption/deferral process ("the exemption process") and the FDA's legal authority to release confidential commercial and/or trade secret information in agency files under that process. CTFA's concerns regarding this issue developed as a result of the promulgation of the OTC drug labeling final rule ("the final rule"), 64 Fed. Reg. 13254, March 17, 1999 which contains the exemption process. 21 C.F.R. § 201.66(e).

The exemption process contemplates a written submission to FDA by a manufacturer justifying the need for an exemption and/or a deferral from parts or all of the OTC drug labeling final rule. Such submissions, which must include, among other things, proposed labeling and graphical and packaging techniques that justify modifications to the required label format, may well contain confidential commercial information and/or trade secret information. The FDA final rule states that "[d]ecisions on exemptions and deferrals will be maintained in a permanent file in this docket for public review". 21 C.F.R. § 201.66(e). In a letter to both CTFA and the Consumer Healthcare Products Association (CHPA) on August 9, 1999, FDA further stated that while certain information in such submissions may be treated as confidential, some aspects of the information may become public when the FDA's decision letter is sent to the manufacturer and made part of the public docket.

1101 17TH ST., N.W., SUITE 300 WASHINGTON, D.C. 20036.4702  
202.331.1770 FAX 202.331.1969  
<http://www.ctfa.org>  
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CTFA's recent presentation was intended, in part, to confirm that FDA would adhere to its legal obligations under the Freedom of Information Act (5 U.S.C. § 552) and FDA's own regulation (21 C.F.R. § 20.1 et seq.) which prohibit public disclosure of such information. We were pleased to hear at the public meeting that FDA's handling of confidential information under this rule would be fully in accord with these requirements. Nonetheless, given the importance of this issue to the industry, we believe it is useful to set forth the law and regulations prescribing FDA treatment of confidential commercial information and trade secret information on agency files.

Prior to discussing FDA's treatment of confidential commercial information and trade secret information, it is important to reiterate CTFA's over-riding concerns regarding the FDA exemption process for OTC drug products, including cosmetic-drugs. CTFA believes that the product label premarket review system contained in the final rule is antithetical to the entire underpinnings of the OTC Drug Review. As FDA acknowledged when it established the OTC Drug Review in 1972, reviewing OTC drugs on a product-by-product basis would be "cumbersome, time consuming and confusing". 37 Fed. Reg. 9484 (May 11, 1972). Among the principal reasons that the OTC Drug Review has been so enormously successful is that companies can conform their products to Monograph Standards and go to market without FDA approval in advance.

This practical effect of an extremely restrictive labeling regulation combined with a case-by-case exemption process runs counter to the entire concept and spirit of the OTC Drug Review. The real solution to the extremely serious problem facing CTFA members who manufacture cosmetic-drugs in small packages as a result of the final rule is to develop feasible general standards for a small package exemption that can be complied with by companies without having to seek permission from FDA to market every product that cannot meet the terms of this regulation. Broader exemption standards would dramatically reduce the number of individual exemption requests that will be necessary, and substantially reduce FDA's role in reviewing confidential materials. In any event, however, it is critical that the manufacturers' trade secret and confidential commercial information be protected when such exemption requests must be filed.

#### The Freedom of Information Act Fully Protects Confidential Commercial Information and Trade Secrets

Companies routinely submit confidential commercial and trade secret information to the FDA. And while the Freedom of Information Act (FOIA) provides a statutory right of access to information, 5 U.S.C. § 552, trade secret and confidential commercial/financial information are specifically exempt from disclosure under exemption 4 of FOIA. Id. at § 552(b)(4). Such information is confidential for purposes of exemption 4 of FOIA if disclosure of the information is likely to: (1) impair the

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Government's ability to obtain necessary information in the future, or (2) cause substantial harm to the competitive position of the person from whom the information is obtained. See Critical Mass Energy Project v. NRC, 975 F.2d 871, 8770-80 (D.C.Cir. 1992) (en banc), cert. denied, 113 S.Ct. 1579 (1993). FDA has routinely withheld both confidential commercial and trade secret information in response to FOIA requests, and when the information meets the definitions, the courts routinely uphold FDA's actions. See Public Citizen Health Research Group v. FDA, 185 F.3d 898 (D.C. Cir. 1999); Public Citizen Health Research Group v. FDA, 704 F.2d 1280 (D.C. Cir. 1983); Webb v. HHS, 696 F.2d 101 (D.C. Cir. 1982).

FDA regulations describe commercial or financial information as "[v]aluable 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". 21 C.F.R. § 20.61(b). Among the types of data FDA recognizes as confidential commercial information are: business sales statistics, customer and supplier lists, research data, profit and loss data, and overhead and operating costs. 60 Fed. Reg. 5530, 5535 (January 27, 1995). In addition, the unique use of colors, labeling, packaging and any innovative product and packaging design features are in fact confidential prior to marketing. The premature release of information related to any of these matters would cause competitive harm.

A trade secret is defined as any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. 21 C.F.R. § 20.61(a).

#### FDA Regulations are Intended to Preserve Confidentiality

Companies rely heavily on FDA's regulations implementing FOIA to ensure full protection of their confidential data. Those regulations provide that information submitted to FDA that falls within the definition of a trade secret or confidential commercial information is not available for public disclosure. 20 C.F.R. § 20.61 (b). FDA routinely declines to release information falling within the FOIA exemptions. 21 C.F.R. § 20.61 (c). While discretionary authority to disclose information otherwise exempt from disclosure is vested in the FDA Commissioner, trade secret and confidential commercial information are not included within the scope of that authority. 21 C.F.R. § 20.82(b)(l).

In addition, the fact that confidential commercial information is voluntarily submitted does not automatically result in a waiver of confidentiality. As discussed above in Critical Mass Energy Project v. NRC, 975 F.2d 871, there is a two-part test to determine confidentiality of voluntarily submitted information. FDA may maintain that the request

for exemption is for the sole benefit of the manufacturer and that the agency has no broader interest in obtaining such information. Nonetheless, the second independent part of this standard of confidentiality remains in force: Will release will cause substantial harm to the competitive position of the person from whom the information is obtained? FDA must not disclose information that meets this standard. To do otherwise violates the FOIA (5 U.S.C. § 552(b)(4)) and FDA's substantive and binding regulations (21 C.F.R. § 20.1 et seq.) which implement that law.

A person who submits records to FDA may designate, in writing, part or all of them as exempt from disclosure under exemption 4 of FOIA. *Id.* at § 20.61(d). In situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, agency regulations require reasonable efforts to notify the person submitting the document of the FOIA request. 21 C.F.R. § 20.61(e)(l). These notification procedures are structured to provide submitters of information the opportunity to object to and defend against improper disclosure of confidential information. *Id.* at § 20.61 (e)(2). If FDA decides to release the requested records, the person submitting the document is again entitled to notification and has 5 days within which to file suit in a United States District Court to enjoin such release. *Id.* at §§ 20.61(e)(2) and 20.46. FDA will keep the contested records confidential until the suit is resolved and all related appeals have been concluded. CTFA anticipates that this procedure will be fully enforced by the agency as part of any exemption process implemented by FDA under this regulation.

#### The Process Has Serious Substantive and Procedural Problems

In addition to CTFA's serious concerns regarding the FDA's handling of confidential commercial information and trade secret information, there are other problems with the OTC drug labeling exemption/deferral process as well. From a procedural standpoint, there are no time frames for review, no clearly delineated appeal process, and no recognition by the agency as to when one of their decisions constitutes final agency action. It is critical that all of these details be defined to ensure that the process is both timely and provides full due process. In addition, the substantive standards for an exemption or deferral (i.e., that the requirement is "inapplicable, impracticable or contrary to public health or safety" (21 C.F.R. § 201.66(c)) need to be defined in greater detail. At present, they are ambiguous standards at best.

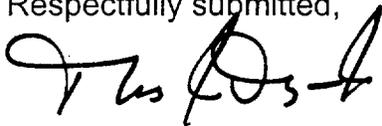
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Conclusion

At its heart, the practical impact of the OTC drug labeling exemption/deferral process as it will have to be used under this regulation is both unfair and flawed. FDA should define a fair set of standards for a small package exemption/deferral and then, consistent with the 25 years of experience from the OTC Drug Review, should allow manufacturers to comply and go to market without having to obtain premarket clearance for a large percentage of their packages.

In any event, FDA must better define the timing and nature of the exemption process and ensure that confidential commercial and trade secret information remain fully protected

Respectfully submitted,



Thomas J. Donegan, Jr.  
Vice President-Legal & General Counsel

cc: Robert DeLap, M.D. (HFD-105)  
Linda M. Katz, M.D. (HFD-560)  
David M. Fox, Esq. (GCF-1)  
Dockets Management Branch (HFA-305)

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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION  
1101 17TH STREET, N.W., SUITE 300  
WASHINGTON, D.C. 20036.4702

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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION  
1101 17TH ST, N.W., SUITE 300 WASHINGTON, D.C. 200364702

Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
ROOM 1061  
Rockville, Maryland 20852