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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

February 20, 2001

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Draft Guidance for Industry on Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals; Availability [Docket No. 00D-1584]

These comments are filed on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA) in response to the Food and Drug Administration's (FDA's) publication of a draft guidance for industry entitled "Labeling OTC Human Drug Products - Submitting Requests for Exemptions and Deferrals" ("Draft Guidance") in the Federal Register of December 19, 2000 (65 FR 79371). For the reasons set forth below we believe that FDA should reconsider this proposed guidance document which falls short of establishing a meaningful standard of review that industry can rely upon.

Founded in 1894, CTFA is the national trade association representing the personal care products industry. CTFA's approximately 300 active members (who manufacture and distribute personal care products) and 300 associate members (who provide related goods and services to the industry) are responsible for providing consumers with the vast majority of personal care products sold in the United States. These products include cosmetics and products such as sunscreens that are regulated both as cosmetics and as drugs.

CTFA has consistently raised concerns about the procedures for requesting a product - specific exemption from or deferral of the new OTC labeling requirements as set forth in section 201.66(e) of the final regulation. Briefly summarized, those concerns are industry's need for FDA to (1) develop criteria for exemptions that are realistic and allow small or innovative packages to remain on the market; (2) create an efficient and expedited process to obtain exemptions; (3) recognize the need for additional procedures to safeguard confidentiality of materials submitted as part of these exemption requests; and (4) provide for a sufficiently speedy decision that will allow companies that must apply for an exemption to compete effectively in a fast-moving marketplace.

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In publishing the Draft Guidance as written, FDA has failed to provide meaningful and realistic guidance to manufacturers who are struggling to implement a rule which is fundamentally flawed by its failure to recognize the enormous variety of existing OTC package sizes that consumers expect and rely on when purchasing OTC products. The Agency's apparent refusal to accommodate legitimate package and labeling concerns is troubling especially given the fact that industry presented its concerns at an OTC Drug Labeling Working Group Meeting on November 23, 1999 and we reiterated them in written comments of December 10, 1999. (A copy of our December 10, 1999 comments is included as Attachment A.) Furthermore, the Agency has been inflexible and unresponsive to the limited number of exemption requests it has received to date. We believe the Agency has lost a valuable opportunity to provide necessary flexibility and relief from the rule as written. Inevitably the consumer will lose, as FDA has not established a meaningful framework for responding efficiently and fairly to manufacturers' needs for the specific reasons set forth below.

FDA's Criteria for Response Times Are Nebulous

The Guidance Document does not provide meaningful guidance for planning purposes. Prompt and efficient communication by the Agency is critical if manufacturers are to implement manufacturing changes in enough time to meet the compliance dates of the OTC labeling rule, in some cases as early as May 16, 2002. FDA's proposed response times of 30 to 60 days for "straightforward requests" and 120 to 180 days for "new or complex issues" (lines 155-156 of the Guidance Document) are vague and impracticable. These terms are not defined or explained by example anywhere in the final OTC labeling rule or Guidance Document. A manufacturer may not know when to expect a response from the Agency to its exemption request (let alone what that response will be) because it cannot determine with certainty what is "straightforward" or "new or complex" to the Agency.

FDA will need to provide sufficient and realistic time frames for manufacturers to implement the approved action steps once an exemption request has been answered. Manufacturing programs are developed and approved often months in advance of implementation. Coordination with suppliers and/or contract manufacturers may further complicate schedules which cannot be established until a manufacturer has learned whether an exemption request has been approved or not. If manufacturers cannot rely on predictable response times, the Agency cannot correspondingly expect industry to implement its decisions on relatively short notice.

FDA Should Provide Guidance for Interpreting the terms "Inapplicable," "Impracticable," and "Contrary to Public Health or Safety" in section 201.66(e)(1)

The Agency has failed to provide further guidance on how it interprets the three regulatory standards: "inapplicable," "impracticable," and "contrary to public health or safety" in section 201.66(e)(1). These standards must be documented, yet FDA has declined to provide any examples of what is meant by each term, or how it will evaluate whether applicants have met them. At a minimum FDA personnel must have a set of concepts or standards for reviewers to base their decisions. Without minimum definitions, examples, or guidelines for these standards, FDA cannot ensure that its reviewers will be fair and consistent in granting or denying exemption requests.

Manufacturers need clearer guidance to evaluate whether they can meet these standards and therefore should apply for an exemption request. Given the tight time frame in which manufacturers must comply, it is unreasonable for FDA to use the public docket as its primary means of providing feedback to industry. This leaves industry's ability to interpret and understand the three regulatory standards: "inapplicable," "impracticable," and "contrary to public health or safety" in section 201.66(e)(1) dependent on an unreliable, case-by-case basis, subject to the unpredictable content of the actual exemption requests FDA receives. FDA needs to be proactive rather than reactive if it is going to hold industry to these ill-defined standards.

FDA Should Permit Off-Label Disclosure of Inactive Ingredients

FDA should consider allowing the disclosure of inactive ingredient information on labeling at the point of purchase to ensure that smaller, "convenience" size products that otherwise conform to the rule as written continue to be available. CTFA has previously proposed that FDA provide the same flexibility to OTC drug products currently afforded to cosmetic products, by allowing ingredient information to be included in labeling "accompanying the product" if the package has a total surface area of less than 12 square inches and is not enclosed in an outer container. See 21 C.F.R. sec. 701.3(i).

FDA has the legal authority to permit off-label disclosure of inactive ingredients under section 412(c) of the FDA Modernization Act of 1997 (FDAMA). Section 412 amended the misbranding provisions of the FD&C Act to require that a drug will be misbranded unless its label bears, among other things, "the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package...." FD&C Act sec. 502(e)(1)(iii). This provision applies to OTC drugs and was incorporated into the final rule establishing a standard format for the labeling of such

products. 64 Fed. Reg. 13254 (1999). However, section 502(e), as amended by FDAMA, did not alter the section of the misbranding provision that states, in pertinent part, "to the extent that compliance with the requirements of subclause ...(iii)...is impracticable, exemptions shall be established by regulations promulgated by the Secretary." Thus, FDA retains the authority to grant relief from the inactive ingredient requirement.

FDA has previously stated that it declined to include in the OTC labeling rule the provision from its cosmetic regulations that allows for the use of an off-label declaration of ingredients under certain circumstances because it conflicts with section 502(e) of the Act. As explained, this does not recognize the statutory authority granted to FDA to establish exemptions from the ingredient labeling requirements by regulation. Accordingly, there is no legal impediment to FDA allowing the disclosure of inactive ingredient information on labeling at the point of purchase to ensure that smaller, "convenience" size products that otherwise conform to the rule as written continue to be available.

Confidentiality Must Be Preserved For FDA to Make Meaningful Decisions in the Exemption Process

In order to explain the need for additional time, manufacturers must be able to provide manufacturing information and production details in confidence outside the public docket. Each manufacturer's production needs and timelines are of great interest to its competitors and therefore must be protected. Reference is made to our comments of December 10, 1999 (Attachment A) which explain in greater detail why information such as the purchase and installation of equipment must be confidential. Such information cannot necessarily be redacted, because it is critical to the Agency's evaluation.

Conclusion

In summary, when a regulatory agency decides, as FDA has here, to manage the details for labeling regulated products, it must establish realistic criteria for compliance that allow companies to compete in the real world. In this instance, FDA has failed to do so and has imposed an inflexible "command and control" structure on the labeling and packaging decisions for these products. Innovation and consumer choice will suffer as a result.

Some OTC products must be labeled in the new format as early as May 16, 2002. Manufacturers have waited for better direction and guidance regarding the exemption process in terms of content, timing, standards of review, and treatment of trade secret or confidential information. We believe that FDA should reconsider this proposed guidance document to provide more useful information and commit to a process that is responsive to manufacturers' and ultimately consumers' needs and expectations.

Respectfully submitted,

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

Attachment

cc: Robert DeLap, M.D. (HFD-105)
Charles J. Ganley, M.D. (HFD-560)
Linda M. Katz, M.D. (HFD-560)
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C T F A

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

ATTACHMENT A

December 10, 1999

E. EDWARD KAVANAUGH
PRESIDENT

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
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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.

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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

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)(1).

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)(1). 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 serous 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.

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

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