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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

April 28, 2003

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

E. EDWARD KAVANAUGH
PRESIDENT

Re: Draft Guidance for Industry on Part 11, Electronic Records, Electronic Signatures—Scope and Application; Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

Docket Nos. 03D-0060, 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539

Dear Sir or Madam:

These comments are submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (CTFA)[1] in response to FDA's publication of "Draft Guidance for Industry on Part 11, Electronic Records, Electronic Signatures—Scope and Application; Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide." (68 Fed. Reg. 8775 [February 25, 2003]).

In the Federal Register of February 25, 2003, the Food and Drug Administration (FDA) announced the availability of a draft guidance for industry entitled "Part 11, Electronic Records; Electronic Signatures--Scope and Application." FDA explained that this action is an outgrowth of its current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics "Pharmaceutical Current Good Manufacturing Practices (CGMPs) for the 21st Century: A Risk Based Approach." FDA explains that this draft guidance is intended to represent the agency's current thinking regarding the scope and application of Part 11. FDA further notes that this action is a re-examination of Part 11 as it applies to all FDA regulated products that may lead to revision of the provisions of Part 11. The draft guidance explains that while this re-examination is under way, FDA intends to exercise enforcement discretion with respect to certain Part 11 requirements. FDA simultaneously announced the withdrawal of Compliance Policy Guide (CPG) 7153.17 and previously published Part 11 draft guidance documents on validation, glossary of terms, time stamps, and maintenance of electronic records.

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[1]CTFA is the national trade association representing the personal care product industry. Founded in 1894, CTFA represents almost 600 companies involved in the sale or distribution of cosmetics, toiletries, fragrances and OTC drugs throughout the world. CTFA represents the manufacturers or distributors of the vast majority of those products sold in the United States. Approximately one-half of CTFA's members are manufacturers or distributors of finished personal care products. The other one-half are suppliers of goods or services to those manufacturers or distributors.

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CTFA is a member of the Industry Coalition on Part 11 that has been working with FDA on Part 11 issues. The Coalition is made up of 14 trade associations representing manufacturers of FDA-regulated products including foods, drugs, cosmetics, veterinary drugs, and medical devices. CTFA supports the comments submitted by the Industry Coalition on Part 11 and will continue to collaborate with this group as the specifics of Part 11 requirements are discussed and clarified. CTFA is submitting these comments supplemental to comments submitted by the Coalition.

Although many of the products of CTFA members are regulated solely as cosmetics and are not affected by this proposal, a very significant number of our members' products are regulated both as cosmetics and as over-the-counter (OTC) drugs. These products, referred to as "cosmetic-drugs" in this document, claim and provide both a cosmetic and a drug benefit. Both such benefits are highly valued by consumers. Products within this category include, but are not limited to (1) antidandruff shampoos, (2) antiperspirant/deodorants, (3) skin protectants, (4) antimicrobial soaps (healthcare antiseptic drug products) and (5) sunscreens, including many traditional cosmetic products such as skin-care products, foundations and lipsticks that contain sunscreens.

For the past 30 years CTFA has actively participated in addressing both the scientific and regulatory issues involved with developing OTC monographs for all product categories that include cosmetic-drug products. For each of these rulemakings, CTFA has filed numerous written comments with FDA, focusing on many of the unique issues facing cosmetic-drug products.

Cosmetic-drugs include many products where there is no dose limitation. Although dosage limitations are typical for most regulated drugs that are also not cosmetics, the absence of an overall dosage limitation for cosmetic-drugs is reflective of the inherently wide safety margins (i.e., the difference between the effective dose and a toxic dose is relatively large) associated with the use of such products. For the purpose of differentiating between dose-limited and non dose-limited drugs, CTFA has proposed in past submissions to define "dosage limitation" as follows:[2]

> "a set of limitations on the size, frequency, and number of doses required in the labeling of a product marketed either pursuant to a Tentative Final Monograph, where applicable, or Final Monograph for an OTC Drug Product Category or a specific New Drug Application approval."

It should be noted that the cosmetic-drugs listed above are regulated in most other jurisdictions as cosmetics even though they are functionally the same as those marketed in the United States. For example, the products identified above are regulated as cosmetics within the European Union. As such, the same level of safety and effectiveness is maintained without the increased level of regulatory oversight that is required for drugs in the US.

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[2]See comments by The Cosmetic, Toiletry, and Fragrance Association on the Food and Drug Administration's Proposed Regulations on Over-The-Counter Drug Labeling, 62 Federal Register 9024 (February 27, 1997) dated October 6, 1997, p. 3.

Summary of Recommendations

CTFA supports the initiative taken by FDA to re-examine the Part 11 requirements and to apply a Risk Assessment approach to CGMPs. This action acknowledges that the same requirements are not appropriate and necessary for all drug products and that safety and efficacy can be achieved through different levels of oversight.

We propose that FDA consider the following factors in developing Part 11 Guidance and in considering the broader application of risk assessment to CGMPs.

(1) cosmetic-drugs present a clear low risk and do not present a risk that would require the same level of oversight that is applied to drugs that are dose restricted or that have a narrow therapeutic margin.

(2) guidance developed by FDA should clearly acknowledge the low risk of these products and take this into account when applying both Part 11 and CGMP regulatory requirements.

(3) FDA should consider alternative approaches for applying Part 11 requirements (and CGMPs) to cosmetic-drugs so that they are not subject to unnecessary and costly systems that are applied to traditional drugs.

(4) FDA investigators should be trained to take into account the intrinsic low risk for these products during GMP inspections.

The development of alternative approaches should allow individual manufacturers to develop and apply their own systems for ensuring the safety and efficacy of cosmetic-drug products.

CTFA appreciates the opportunity to provide these comments and looks forward to working with the agency to explore regulatory approaches to cosmetic-drugs that are more aligned with their risk. Please feel free to contact us if you have questions or need additional information.

Respectfully submitted,

E. Edward Kavanaugh
President

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