

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 2006N-0479]

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Insect Repellent-Sunscreen Drug Products for Over-the-Counter Human Use; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is seeking information to formulate a regulatory position on insect repellent products that contain over-the-counter (OTC) sunscreen ingredients. FDA is considering amending its monograph for OTC sunscreen drug products (the regulation that establishes conditions under which these drug products are generally recognized as safe and effective and not misbranded) to add conditions for marketing insect repellent-sunscreen drug products. The insect repellent ingredients in these products are regulated by the Environmental Protection Agency (EPA). Elsewhere in this issue of the **Federal Register** is a companion document in which EPA is also requesting information and comments on these products. The decision on what regulations, if any, to propose will be based, in part, on information and comments submitted in response to this request for data and information.

DATES: Submit written or electronic comments by *[insert date 90 days after date of publication in the Federal Register]*.

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ADDRESSES: You may submit comments, identified by Docket No. 2006N-0479 or RIN 0910-AF43, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management (HFA-305), Food and Drug Administration,
5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. and Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Matthew R. Holman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, MS 5411, Silver Spring, MD 20993, 301-796-2090.

SUPPLEMENTARY INFORMATION:

I. Background

A. Description of Insect Repellent-Sunscreen Drug Products

FDA and EPA are seeking information to formulate a regulatory position for combination insect repellent-sunscreen drug products for use on human skin. Because sunscreen drug products are regulated by FDA and the insect repellent components of these products are separately regulated by EPA, both agencies are seeking comments to determine how these combination products should be regulated.

Currently, approximately 20 combination insect repellent-sunscreen drug products are available for consumers. These products consist of one of three insect repellents (N,N-diethyl-meta-toluamide (DEET), oil of citronella, or IR3535) and a sunscreen component (one or more sunscreen ingredients). Combination insect repellent-sunscreen drug products are available in lotion, cream, and spray-on formulations and are currently marketed for use by the entire family. Due to concerns about the potential conflict in the directions for use and other labeling requirements for the insect repellent and the sunscreen components of the product, EPA postponed a regulatory decision

on combination DEET/sunscreen products in its Reregistration Eligibility Decision (RED) for DEET (December 1998) until additional information could be obtained. This document solicits opinion and comment from the public to assist both agencies in regulating these products.

B. Regulatory Status of the Insect Repellent Ingredients

EPA regulates insect repellents under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Three insect repellent active ingredients are currently used in combination with sunscreens: DEET, oil of citronella, and IR3535. EPA recently registered two other insect repellents, p-menthane-3,8-diol and picaridin. However, neither is currently available in combination with a sunscreen. Both DEET and oil of citronella have undergone reregistration, which entailed an evaluation and analysis of the complete database for each ingredient by EPA. IR3535, p-menthane-3,8-diol, and picaridin are registered chemicals evaluated by the registration process, which involves a similar analysis by EPA. They have not yet undergone the reregistration analysis.

1. DEET

In December 1998, EPA completed its RED for DEET (Ref. 1), which includes the active ingredient N,N-diethyl-meta-toluamide and its isomers. DEET products, which are applied directly to skin and/or clothing, are available in numerous formulations (e.g., aerosol and non-aerosol sprays, creams, lotions, sticks, foams, and towelettes) and concentrations (products range from about 4 percent to 100 percent active ingredient). DEET is an insect and mite repellent labeled for use in households/domestic dwellings, on the human body and clothing, on cats, dogs, and horses, and in pet living/sleeping quarters.

Based on pesticide usage information mainly for 1990 (Ref. 1), an average annual estimate of the domestic usage of DEET is 4 million pounds (active ingredient). About 30 percent of the U.S. population uses DEET annually as an insect repellent (this figure includes about 27 percent of adult males, 31 percent of adult females, and 34 percent of children). Approximately 21 percent of U.S. households use DEET annually. About 19 percent of households use DEET on household members, and about 4 percent of households that have cats and/or dogs use DEET on those pets.

EPA indicated in its DEET RED (Ref. 1):

The Agency is concerned about consumer use of products that combine sunscreen and DEET, since directions to reapply sunscreens generously and frequently may promote greater use of DEET than needed for pesticidal efficacy and thus pose unnecessary exposure to DEET. DEET labels currently recommend that products be used sparingly and not be reapplied too often. Sunscreen products, however, recommend frequent reapplication. No benefits attach to use of DEET more frequently than necessary to achieve its purpose.

EPA did not make a regulatory decision regarding these DEET-sunscreen products at that time because it believed that it had not yet obtained adequate information.

2. Oil of Citronella

In February 1997, EPA completed its RED for Oil of Citronella (Ref. 2). This decision includes a comprehensive reassessment of the required target data and the use patterns of currently registered oil of citronella products. Oil of citronella is a biochemical pesticide. It is registered as an animal repellent and as an insect repellent/feeding depressant. Oil of citronella is the volatile oil obtained from the steam distillation of freshly cut or partially dried grasses

(*Cymbopogon nardus* (Rendal) and *Cymbopogon winterianus* (Jowitt)). Two varieties of citronella oil exist commercially: "Ceylon type" (derived from *C. nardus*) and "Java type" (derived from *C. winterianus*).

Based on pesticide survey usage information for 1991 and 1992 (Ref. 2), annual oil of citronella domestic usage ranged approximately from 33,000 to 48,000 pounds active ingredient for four sites: Domestic dwellings; ornamentals; human face, skin, and clothing; and manufacturing. The largest markets, in terms of total pounds active ingredient, for oil of citronella as an insect repellent are: Human face, skin, and clothing (56 to 74 percent); domestic dwelling [outdoor] (22 to 41 percent); and ornamentals (1.5 to 2.0 percent). The balance is used for manufacturing.

In the RED (Ref. 2), EPA required all oil of citronella products with label claims for repelling mosquitoes, fleas, and ticks to have a minimum protection time of 1 hour. The directions for use must also contain the following statement pertaining to maintenance of repellent activity: "For maximum repellent effectiveness of this product, repeat applications at 1 hour intervals." The RED allows the labeling to claim a protection time longer than 1 hour so long as it can be supported by product performance data showing an acceptable level of repellent activity. Because the principal uses of oil of citronella are dermal, special precautionary labeling related to dermal sensitization and irritation is required for all products with use directions for dermal application. EPA (Ref. 2) requires oil of citronella-sunscreen products for dermal application to bear the following precautionary statements regarding dermal sensitivity: "For external use only. Avoid contact with eyes. Discontinue if irritation or rash appears. Use on children under 6 months of age only with the advice of a physician." These precautionary statements are

consistent with the warnings and directions (regarding use on children under 6 months of age) that appear in FDA's stayed monograph for OTC sunscreen drug products (part 352 (21 CFR part 352)).

3. IR3535

The third currently registered insect repellent used in combination with a sunscreen is IR3535 (CAS number 52304-36-6). In 1997, EPA classified IR3535 as a biochemical for the following reasons (Ref. 3): (1) It is functionally identical to naturally occurring beta-alanine, (2) both ingredients repel insects, (3) their basic molecular structure is identical, (4) the end groups are not likely to contribute to toxicity, and (5) IR3535 acts to control the target pest via a nontoxic mode of action. IR3535 is a technical grade synthetic biochemical pesticide that is produced by an integrated process. It is a liquid containing 98 percent 3-[N-Butyl-N-acetyl]-aminopropionic acid, ethyl ester as the active ingredient and 2 percent inert ingredients.

4. p-menthane-3,8-diol and KBR 3023

There are two insect repellent active ingredients that are not currently used in a combination insect repellent-sunscreen drug product. However, for the purposes of completeness, all currently registered insect repellents are discussed within this document.

The first ingredient is p-menthane-3,8-diol, a biochemical pesticide that is chemically synthesized, although the natural oil can be extracted from lemon eucalyptus leaves and twigs (Ref. 4). It can be used in spray and lotion products to repel insects such as mosquitoes.

The other insect repellent is KBR 3023, which contains the active ingredient picaridin. This chemical is currently formulated only for application to human skin. In December 2000, EPA registered a 15 percent pump-spray,

10 percent aerosol spray, 7 percent cream, 7 percent pump-spray, 5 percent cream, and 5 percent pump-spray (Ref. 5).

C. Regulatory Status of the Sunscreen Ingredients

In the **Federal Register** of May 21, 1999 (64 FR 27666), FDA issued a final monograph for OTC sunscreen drug products in part 352, establishing conditions under which these products are generally recognized as safe and effective and not misbranded. The monograph includes 16 sunscreen active ingredients in § 352.10; provides for combinations of sunscreen active ingredients in § 352.20; specifies required labeling in §§ 352.50, 352.52, and 352.60; and sets forth required testing procedures in §§ 352.70 through 352.77. Once the monograph becomes effective, any drug product (including any combination insect repellent-sunscreen drug product) that contains unsuitable inactive ingredients or active drug ingredients that do not comply with the monograph will be considered a new drug and require an approved new drug application (NDA) before it may be legally marketed in the United States.

Initially, the final monograph was to become effective on May 21, 2001, but FDA subsequently extended that date to December 31, 2002 (65 FR 36319, June 8, 2000). FDA then stayed the effective date of the monograph until further notice (66 FR 67485, December 31, 2001). FDA has delayed this effective date as it prepares an amendment to part 352 to address formulation, labeling, and testing requirements for ultraviolet A (UVA) radiation protection and to revise some of the requirements for ultraviolet B (UVB) radiation protection in a more comprehensive final monograph.

Historically, FDA has used its enforcement discretion to allow the marketing of insect repellent-sunscreen drug products pending the issuance of the final sunscreen monograph so long as the products contained sunscreen

ingredients included in the FDA rulemaking and were registered with EPA. These types of products were first marketed before the OTC drug review began in 1972, and FDA has not explicitly addressed them at any time in the rulemaking for OTC sunscreen drug products. Because they have always contained a pesticide, the combination insect repellent-sunscreen products have also historically been registered with and regulated by EPA.

FDA is now interested in determining whether it should further amend that monograph to address these combination products. Once the final monograph for sunscreen drug products becomes effective, any combination product containing an unsuitable inactive ingredient or an active drug ingredient that is not included in the final monograph will be considered a new drug and need an NDA to be legally marketed, even if the product is also registered with EPA. Thus, one purpose of this document is to gather information to help FDA formulate its regulatory position toward these combination products.

D. Regulatory Jurisdiction Over Insect Repellent-Sunscreen Drug Products

In the **Federal Register** of December 22, 1971 (36 FR 24234), the Department of Health, Education, and Welfare (DHEW) and EPA published a Memorandum of Agreement (the Agreement) regarding matters of mutual responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the FIFRA. The Agreement was amended in the **Federal Register** of September 6, 1973 (38 FR 24233). This Agreement does not explicitly address products that combine sunscreen and insect repellent active ingredients. As noted, one purpose of this document is to solicit comments regarding the complexities of joint jurisdiction of these combination products.

II. Information Requested and Specific Topics for Comment

Interested persons are asked to review and comment upon all aspects of both FDA's and EPA's documents. Interested persons should submit all comments to both agencies. Both agencies have potential safety and effectiveness concerns for some of these products because of the different intervals of time required or recommended between applications of sunscreens versus insect repellents. FDA is particularly interested in receiving comments on the following topics:

A. Possible Manufacturing Conflicts

Because they contain ingredients regulated by EPA and FDA, all insect repellent-sunscreen drug products currently need to comply with both EPA's testing and laboratory requirements in 40 CFR part 158 and FDA's current good manufacturing practice for finished pharmaceuticals requirements in part 211 (21 CFR part 211). The products will also have to meet the testing procedures for OTC sunscreen drug products in part 352, subpart D, when that monograph becomes effective. The agencies are not aware of any specific manufacturing requirements that conflict and invite specific comment and information on this subject.

1. Are manufacturers of insect repellent-sunscreen drug products or others aware of any conflicts between the EPA and FDA manufacturing requirements for these products? If yes, is there any way to resolve the conflict(s)?

2. Approximately 20 insect repellent-sunscreen drug products are currently registered with EPA. If there is a future FDA rulemaking for all combination insect repellent-sunscreen drug products, how should these currently registered products be addressed in the sunscreen monograph? What

requirements should be retained, revised, or eliminated from the sunscreen monograph?

3. Have manufacturers of currently marketed insect repellent-sunscreen drug products conducted any of the testing described in part 352, subpart D, for their combination product(s), notwithstanding that the effective date of part 352 has been stayed? If yes, what problems, if any, have they encountered?

B. Possible Formulation Conflicts

During completion of its DEET RED, EPA solicited information from registrants of insect repellent-sunscreen drug products on the possibility of formulation conflicts. At that time, EPA received information that suggests a potential formulation conflict is encountered when sunscreen and insect repellent are used separately (or sequentially applied) (Ref. 6). It is unclear whether this formulation issue poses a similar or related problem when these ingredients are combined into a single product. The agencies invite specific comment and information on this subject.

C. Possible Labeling Conflicts

Insect repellent and sunscreen products each have different labeling requirements that may conflict when both are combined and packaged in one product. The insect repellent component is subject to the labeling requirements in 40 CFR 156.10 entitled "labeling requirements and the active ingredient specific requirements." For each registered insect repellent, these requirements are listed in the registration or reregistration documents. The sunscreen component of the product is subject to the labeling requirements in § 201.66 (21 CFR 201.66) and part 352. However, FDA has stayed these regulations for OTC sunscreen drug products until we issue a sunscreen final rule (69 FR 53801 (September 3, 2004) and 66 FR 67485).

The agencies are concerned that the labeling format and some of the content requirements vary between the EPA and FDA requirements. For example, FDA uses the word "warning" on labels, while EPA uses the word "caution" and only uses the word "warning" as an indicator of toxicity level on pesticide labels. Many of the required warning section headings are also different. In addition, the application directions for the sunscreen and the insect repellent components may be significantly different. For example, the application directions for sunscreens state to "apply liberally (or generously) * * * as needed" and provide for application to more areas of the body than do the application instructions for insect repellents, which tend to restrict the frequency of application and where and how the product can be applied.

EPA requirements for DEET include labeling that states: "Apply sparingly around ears." and "Do not apply to children's hands." The directions for some DEET products require a 6-hour interval between applications and state: "Use just enough repellent to cover exposed skin and/or clothing" and "avoid over-application of this product." Also, a currently marketed insect repellent (DEET)-sunscreen drug product states in its labeling "frequent reapplication and saturation is unnecessary for effectiveness." While frequent reapplication may not be necessary for the effectiveness of the DEET in this product, frequent reapplication may be necessary for the effectiveness of the sunscreen.

Hence, there are many differences between the labeling required by FDA for OTC drugs and EPA for pesticides. The labeling formats, labeling content, and the order in which information is presented are quite different. FDA and EPA are exploring whether they can reconcile these differences, safeguard the public health, and still adequately meet the requirements of FFDCA and FIFRA.

1. Concerning an integrated label, can the different instructions for the two components (regarding frequency of application and where the product can be applied) be reconciled into a single direction that does not lead to improper application (i.e., incorrect location), over-application of the insect repellent, or under-application of the sunscreen? Is there labeling that would reflect the differences in reapplication intervals for DEET when combined with sunscreen ingredients? Oil of citronella when combined with sunscreen ingredients? IR3535 when combined with sunscreen ingredients?

2. The FFDCA requires that all OTC drug products list the established name of each inactive ingredient on the outside container of the retail package (see section 502(e)(1)(A)(iii) of FFDCA (21 U.S.C. 352(e)(1)(A)(iii)); also see § 201.66(c)(8)). EPA does not require a complete declaration of “inactive or inert” ingredients and normally does not require insect repellent manufacturers to list the identities of inert ingredients on product labels. However, under FIFRA, if one inert ingredient is disclosed in product labeling, then all inert ingredients must be disclosed. EPA is currently discussing, with a wide spectrum of stakeholders, how to make information concerning inert ingredients more widely available. The results of those discussions will affect combination insect repellent-sunscreen drug products as well as other pesticide products. Failure to list all of the inactive ingredients in the product's labeling, including all such ingredients in the insect repellent, would cause a combination insect repellent-sunscreen drug product to be misbranded under the FFDCA (see section 502(e)(1)(A)(iii) of FFDCA). Is there a way to label combination sunscreen-insect repellent drug products that satisfies FFDCA's requirements under section 502(e)(1)(A) of FFDCA but does not violate FIFRA?

Are those ingredients that are “inert” under FIFRA also necessarily “inactive” under FFDCA?

D. Safety Issues

FDA is aware of only two studies examining percutaneous absorption when combining an insect repellent with a sunscreen. One study involved hairless mice (Ref. 6) and the other study involved piglets (Ref. 7). Both studies demonstrate increased absorption of the insect repellent DEET and different sunscreens when the components were combined. Thus, FDA would like more information concerning the safety of insect repellent-sunscreen drug products:

1. Is there data available to show whether increased absorption of the sunscreen ingredients(s) does or does not occur as a result of being combined with an insect repellent ingredient? If so, please provide. For example, is there any evidence that absorption increases as the particle size of titanium dioxide and zinc oxide decreases (down to a few nanometers) in insect repellent-sunscreen products? If so, is there evidence regarding the health or safety effects associated with the increased absorption?

2. Are there reports or other information relating to skin irritation resulting from use of a combination insect repellent-sunscreen drug product are manufacturers of these products or others aware of? Provide a summary of the types of events reported and, if possible, estimate an incidence of occurrence.

E. Effectiveness Issues

For some insect repellent-sunscreen products, FDA has effectiveness concerns because of the interval of time required or recommended between applications of the product. EPA identifies reapplication times on insect repellent labels so consumers can maintain the maximum protection against insect bites but avoid over-exposure. This reapplication time relates to the

effectiveness of the insect repellent portion of the product and not to the sunscreen protection. The directions for sunscreen products, which encourage frequent reapplication of the drug, relate to the effectiveness of the sunscreen component of the product and not to the insect repellent component.

The differences in directions for use for the insect repellent component and the sunscreen component need to be resolved to ensure safety and effectiveness of both components and the combination product as a whole. For example, the directions for some products containing DEET require a 6-hour interval between applications and state “use just enough repellent to cover exposed skin and/or clothing” and “avoid over-application of this product.” In contrast, the directions for sunscreen drug products in § 352.52(d)(1) and (d)(2) state to “apply liberally, generously, smoothly, or evenly * * * before sun exposure and as needed,” and “reapply as needed or after towel drying, swimming, or (select ‘sweating’ or ‘perspiring’).” Section 352.60(d) of the sunscreen monograph also states that “when the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.”

Concerns about effectiveness also stem from a study (Ref. 8) indicating that separate application of sunscreen followed by DEET resulted in a decrease in sun protection factor (SPF) after application of the insect repellent. Thus, FDA is soliciting comment on the following questions:

1. Is there additional evidence suggesting that application of a sunscreen product followed by application of a separate insect repellent product results

in a decrease in the sunscreen's SPF? Is there evidence suggesting that sequential application of the products has no adverse effect on the sunscreen?

2. Is there evidence suggesting that combining a sunscreen and insect repellent in a single formulation adversely impacts the effectiveness of the sunscreen? Is there evidence suggesting that such a combination has no adverse impact on the sunscreen component?

3. Are there effective concentrations of the insect repellent ingredients that could be used to allow for liberal application and frequent reapplication of the insect repellent-sunscreen drug products, as directed by the sunscreen directions, without jeopardizing the safety of the consumer? How does this vary by insect repellent ingredient? Would any of the insect repellent ingredients be effective at such concentrations?

4. Is there information available to show whether there are any chemical or physical incompatibilities between insect repellent and sunscreen active ingredients when used in combination products or when used separately? Are there any sunscreen ingredients that should not be used with a specific insect repellent ingredient?

5. If an insect repellent ingredient (e.g., DEET) is labeled for 6-hour intervals between applications, can the effectiveness of the sunscreen be assured if the product cannot be applied more often than every 6 hours? Is there a need for a minimal SPF to assure the effectiveness of the combination product considering the wide variation in minimal erythema dose (MED) between individuals and the need for reapplication due to physical stress such as toweling or rubbing of the skin? If the answer is yes, what minimal SPF value should be required, and what is the basis for that SPF value?

6. Is there information available to demonstrate that there are product performance benefits [other than the convenience of using one product instead of two] derived from the concurrent application of the insect repellent and the sunscreen (as opposed to sequential application of these products separately)? Please submit any data that you reference.

7. Oil of Citronella products are labeled to repeat applications at 1 hour intervals for maximum repellent effectiveness. Is it possible that insect repellent-sunscreen drug products can be formulated in such a way that the insect repellent reapplication intervals coincide more closely with the sunscreen reapplication intervals? Can this be done without jeopardizing the safety or effectiveness of these products?

III. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on this document. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. EPA Reregistration Eligibility Decision for DEET, 1998.
2. EPA Reregistration Eligibility Decision for Oil of Citronella, 1997.

3. EPA Biopesticide Registration Eligibility Document for IR3535, 1999.
4. EPA Biopesticide Registration Eligibility Document for p-menthane-3,8-diol, 2000.
5. EPA Decision Memorandum on KBR 3023, 2000.
6. Ross, E. A. et al., "Insect Repellent Interactions: Sunscreens Enhance DEET (*N,N*-Diethyl-*M*-Toluamide) Absorption," *Drug Metabolism and Disposition*, 32:783–785, 2004.
7. Gu, X. et al., "In Vitro Evaluation of Concurrent Use of Commercially Available Insect Repellent and Sunscreen Preparations," *British Journal of Dermatology*, 152: 1263–1267, 2005.
8. Montemarano, A. D. et al., "Insect Repellents and the Efficacy of Sunscreens," *The Lancet*, 349:1670–1671, 1997.

This request for information and comment is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act

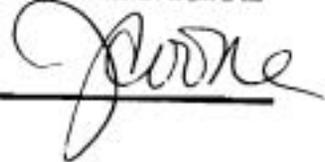
(21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under authority of the
Commissioner of Food and Drugs.

Dated: 12/5/06
December 5, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

**CERTIFIED TO BE A TRUE
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