DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 348

[Docket No. 78N-0301]

Male Genital Desensitizing Drug Products for Over-the-Counter Human Use; Proposed Rule

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking to amend the tentative final monograph for over-the-counter (OTC) external analgesic drug products to establish conditions under which OTC male genital desensitizing drug products (premature ejaculation remedies) are generally recognized as safe and effective and not misbranded. (See the Federal Register of February 8, 1983; 48 FR 5852.) FDA is issuing this notice of proposed rulemaking after considering the statement on OTC male genital desensitizing drug products of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on an advance notice of proposed rulemaking that was based on that statement. This proposal s part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by December 2, 1985. New data by October 2, 1986. Comments on the new data by December 2, 1986. These dates are consistent with the time periods specified in the agency's revised procedural regulations for reviewing and classifying OTC drugs (21 CFR 330.10). Written comments on the agency's economic impact determination by January 30, 1986.

ADDRESS: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center For Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 7, 1982 (47 FR 39412), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to amend the monograph for OTC external analgesic drug products, together with the recommendations on OTC male genital desensitizing drug products of the Advisory Review Panel on OTC Miscellaneous External Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients used as male genital desensitizers. That notice also reopened the administrative record for OTC external analgesic drug products to allow for consideration of the Miscellaneous External Panel's statements on OTC drug products intended for use as male genital desensitizers. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

In response to the advance notice of proposed rulemaking, two drug manufacturers and one trade association submitted comments. Copies of the comments received are on public display in the Dockets Management Branch.

In order to conform to terminology used in the OTC drug review regulations (21 CFR 330.10), the present document is designated as a "tentative final monograph." Its legal status, however, is that of a proposed rule. The Panel proposed certain external analgesic active ingredients for use as male genital desensitizers. In this tentative final monograph (proposed rule) to amend Part 348 (21 CFR part 348), FDA states for the first time its position on the establishment of a monograph for OTC external analgesic drug products for use as male genital desensitizers and proposes to amend the tentative final monograph for OTC external analgesic drug products to include certain external analgesic active ingredients for use as male genital desensitizers. Final agency action on this matter will occur with the publication at a future date of a final monograph, which will be a final rule establishing a monograph for OTC external analgesic drug products for use as male genital desensitizers.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC external analgesic drug products for use as male genital desensitizers as modified on the basis of comments received and the agency's independent evaluation of the Panel's statement. Modifications have been made for clarity and regulatory accuracy and to reflect new information. Such new information has been placed on file in the Dockets Management Branch (address above). These modifications are reflected in the following summary of the comments and FDA's responses to them. (See Part I below.)

The OTC procedural regulations (21 CFR 330.10) have been revised to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). (See the Federal Register of September 29, 1981; 46 FR 47730.) The Court in *Cutler* held that the OTC drug review regulations were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision has been deleted from the regulations, which now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA). Further, any OTC drug products

subject to this monograph that are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In the advance notice of proposed rulemaking published in the **Federal Register** of September 7, 1982, the agency suggested that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register.**

Therefore, the agency is proposing that the final monograph be effective 12 months after the date of its publication in the **Federal Register.** The agency believes that within 12 months after the date of publication most manufacturers can order new labeling and reformulate their products and have them in compliance in the marketplace. However, if the agency determines that any labeling for a condition included in the final monograph should be implemented sooner, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch.

I. The Agency's Tentative Conclusions on the Comments

A. General Comments.

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464) and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated there. Subsequent court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. See, e.g., *National Nutritional Foods Association* v. *Weinberger,* 512 F. 2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA,* 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd,* 637 F. 2d 887 (2d Cir. 1981).

2. Noting its continued opposition to the exclusivity policy, one comment stated that FDA should not prohibit the use of alternative OTC labeling terminology to describe indications, if the terminology is truthful, not misleading, and intelligible to the consumer. The comment's views on this subject were presented in oral and written testimony submitted to FDA in connection with the September 29, 1982 FDA hearing on the exclusivity policy.

During the course of the OTC drug review, the agency has maintained that the terms that may be used in an OTC drug product's labeling are limited to those terms included in a final OTC drug monograph. (This policy has become known as the "exclusivity rule.") The agency's position has been that it is necessary to limit the acceptable labeling language to that developed and approved through the OTC drug review process in order to ensure the proper and safe use of OTC drugs. The agency has never contended, however, that any list of terms developed during the course of the review exhausts all the possibilities of terms that appropriately can be used in OTC drug labeling. Suggestions for additional terms or for other labeling changes may be submitted as comments to proposed or tentative final monographs within the specified time periods or through petitions to amend monographs under § 330.10(a)(12).

During the course of the review, FDA's position on the "exclusivity rule" has been questioned many times in comments and objections filed in response to particular proceedings and in correspondence with the agency. The agency has also been asked by The Proprietary Association to reconsider its position. In a notice published in the **Federal Register** of July 2, 1982 (47 FR 29002), FDA announced that a hearing would be held to assist the agency in resolving this issue. On September 29, 1982, FDA conducted an open public forum at which interested parties presented their views. The forum was a legislative type administrative hearing under 21 CFR Part 15 that was held in response to a request for a hearing on the tentative final monographs for nighttime sleep-aids and stimulants (published in the **Federal Register** of June 13, 1978; 43 FR 25544).

After considering the testimony presented at the hearing and the written comments submitted to the record, in the **Federal Register** of April 22, 1985 (50 FR 15810), FDA proposed to change its exclusivity policy for the labeling of OTC drug products. As proposed, manufacturers may select one of the following options:

(1) The label and labeling would contain within a boxed area designated "APPROVED USES" the specific wording on indications for use established under an OTC drug monograph. The boxed area would be required to be displayed in a prominent and conspicuous location. As under the present policy, the labeling in the boxed area would be required to be stated in the exact language of the monograph. However, with this option a statement that the information in the box was published by the Food and Drug Administration would appear either in the box or reasonably close by. At the manufacturer's option, the designation of the boxed area and the statement that the labeling was established by FDA could be combined.

(2) As a complete alternative to using the boxed area designated "APPROVED USES," the proposal would for the first time allow manufacturers an option to use other truthful and nondeceptive statements relating only to the indications established in an applicable monograph subject to the prohibitions in section 502(a) of the act against misbranding by the use of false or misleading labeling. If this alternative is selected, the manufacturer would not be able to use a boxed area or include a statement that the indications are endorsed by the Food and Drug Administration.

(3) As a third alternative, manufacturers could use both a boxed area with the monograph language and also, elsewhere in the labeling, use other non-monograph language that meets the statutory standards of truthfulness and accuracy.

Regardless, other aspects of OTC drug labeling, such as the statement of identity, warnings, and directions, would continue to be required to comply with the monograph, including following any exact language established in the monograph.

The proposal to change the exclusivity policy provides for 90 days of public

comment. After considering all comments submitted, the agency will announce its final decision on this matter, in a future issue of the Federal Register.

B. Comments on Ingredients and Labeling.

3. One comment disagreed with the warning recommended by the Miscellaneous External Panel on male genital desensitizing drug products containing benzocaine. The warning states "Use this product with caution if you or your partner are sensitive to topical anesthetics, sunscreens, sulfa drugs, or hair dyes." The comment quoted the Panel's statement on male genital desensitizers in which the Panel discussed the incidence of benzocaine sensitivity. The comment further cited references identified by the Panel that found the incidence of benzocaine sensitivity to be 5 percent in patients with a history of chronic skin disorders and 0.17 percent in a general population study. The comment cited other references in the Panel's statement, which concluded that "reported adverse reactions to benzocaine have not been considered in relation to the total number of repeated applications of the drug . . ."; "instances of cross sensitivity among the local anesthetics are rare regardless of the mode of administration"; and "contact dermatitis occurs more frequently on the skin than on mucous membranes." The comment pointed out that despite these findings the Panel based its recommendation largely on a study by Fisher (Ref. 1) who stated that benzocaine is a potent sensitizer. The comment also cited the external analgesic advance notice of proposed rulemaking (44 FR 69795) in which the Panel concluded that benzocaine is one of the most widely use and safest external analgesic ingredients in OTC use and that the incidence of sensitivity to benzocaine is quite low. The comment argued that it would be inconsistent for the warning to apply to products used in a similar manner for different indications. The comment further argued that in the advance notice of proposed rulemaking for anorectal drug products published in the Federal Register of May 27, 1980 (45 FR 35576) and in the information copy of the report on vaginal drug products, a sensitivity warning was required on benzocaine because these products are used on irritated, not normal skin.

The agency agrees with the comment that there is a low potential of benzocaine sensitivity in the general population. The Topical Analgesic Panel, in its advanced notice of proposed rulemaking on external analgesic drugs, published in the Federal Register of December 4, 1979 (44 FR 69768), did not include a specific warning for benzocaine but instead proposed the following warning for all external analgesic ingredients: "Discontinue use if condition worsens or if symptoms persist for more than 7 days, and consult a physician." The agency agreed with the Panel in the tentative final monograph (48 FR 5852). The agency also notes that the Miscellaneous External Panel in its statement on male genital desensitizers proposed a general warning "If skin to which you apply this product becomes irritated, discontinue use and consult a doctor" and a specific warning for benzocaine "Use this product with caution if you or your partner are sensitive to topical anesthetics, sunscreens, sulfa drugs, or hair dyes" (47 FR 39433). Although agreeing with the first warning, the agency finds a lack of sufficient information to support a specific warning for benzocaine. In addition, consideration must be given to the intended use of these products on healthy, intact skin and mucous membranes. Therefore, based upon a review of the two panel recommendations, and the intended use of these products, the agency proposes to further clarify the general warning for all male genital desensitizing drug products to state "If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor."

The agency believes that the revised warning is more meaningful and provides adequate information for safe use. The agency proposes to include the labeling on all male genital desensitizing products.

Reference

(1) Fisher, A., "Contact Dermatitis," 2d Ed., Lea and Febiger, Philadelphia, pp. 42, 312, and 313, 1973.

4. A comment requested that products containing a complex of camphor and metacresol in a ratio of 3 parts camphor to 1 part metacresol be placed in Category I for use as male genital desensitizers. The comment did not include information on the concentration of camphor and metacresol contained in these products. The comment stated that the chemical complex of these two ingredients is well suited for this use because of the complex's properties of (1) low surface tension which allows it to penetrate unbroken skin, (2) controlled release of metacresol from the complex which limits the total available amount of free metacresol to less than 2 percent at any given time, (3) strong desensitizing and anesthetizing effect, and (4) effective fungicidal, sporicidal, and antiseptic properties. The comment incorporated, by reference, its previous submissions of studies and clincial tests to the external analgesic rulemaking to substantiate the points listed above.

The agency is unaware of the use of this complex as a male genital desensitizing agent in any commercially marketed OTC drug product in the United States. Such a product would, therefore, be a new drug as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act). Marketing of a male genital desensitizing agent containing this complex in the absence of an approved new drug application would be in violation of section 505(a) of the act unless and until the agency placed the complex for this use in Category I for safety and efficacy in the final monograph covering male genital desensitizing agents.

In addition, the agency notes that camphorated metacresol was classified in Category I in the tentative final monograph for external analgesics for use in the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites, or minor skin irritations (48 FR 5858). Benzocaine and lidocaine, which were classified by the Miscellaneous External Panel in Category I for use as male genital desensitizers, are identified at § 348.10(d) as external analgesic active ingredients that depress cutaneous sensory receptors (47 FR 39432). These same ingredients are grouped in the external analgesic TFM under § 348.10(a) *amine and "caine"-type local anesthetics* (48 FR 5867). Camphorated metacresol is grouped into § 348.10(b) *alcohols and ketones* (48 FR 5867). While ingredients of both groups (a) and (b) are effective in relieving pain and itching, only those in group (a) are known to also exert an anesthetic effect.

An anesthetic (or desensitizing) effect is necessary for use as a male genital desensitizer. There are no efficacy data available demonstrating such an effect for camphorated metacresol. In addition, the agency disagrees with the comment that the complex of camphor and metacresol is safe for use as a male genital desensitizer. The comment submitted no data to establish the safety on mucous membranes or for use intravaginally. The earlier submissions which the comment incorporated by reference were discussed previously in the external analgesic tentative final monograph published in the Federal Register of February 8, 1983 (48 FR 5852) which classified camphorated metacresol in Category I for the label

claims noted above. However, the earlier submissions do not support safety and effectiveness for use as a male genital desensitizer. Accordingly, based upon a lack of marketing experience or data to support safe and effective use as a male genital desensitizer, camphorated metacresol is classified in Catgeory II for safety and effectiveness for this use.

5. One comment requested that lidocaine for use as a male genital desensitizer not be limited to a container size of 120 milligrams (mg). The comment stated that this restriction is scientifically ungrounded, legally unsupportable, and commercially impracticable. The comment argued that the 120 mg capacity limitation was not needed because quantities substantially exceeding 120 mg have been applied to the genital area as local anesthetic during childbirth, without adverse effects, and therefore should be considered as safe. The comment also argued that there is no reason from a legal standpoint to limit the container size for an ingredient classified in Category I, i.e., not misbranded. Rather, concerns about misuse or abuse and restrictions on usage should be dealt with through labeling requirements.

The agency agrees with the comment. The agency has reviewed the Panel's recommendation and finds insufficient evidence for a container size limitation for lidocaine. The Panel's container size limitation of 120 mg lidocaine was based on the maximum dose of 10 sprays of 10 mg each with an allowance for variation as would normally occur in manufacturing. However, the agency is not aware of marketed aerosol products with this small capacity. Further, the product submitted to the Panel (Refs. 1 and 2), contained 7/16 ounce of product which contains approximately 1,200 mg of lidocaine. No adverse reactions attributable to misuse or abuse of this product have been reported to the agency. The Topical Analgesic Panel, in its external analgesic advance notice of proposed rulemaking published in the Federal Register of December 4, 1979 (44 FR 69768), concluded that lidocaine was Category I without a container size limitation. The agency agreed with that conclusion in the tentative final monograph, published in the Federal Register of February 8, 1983 (48 FR 5852). The agency believes that the dose limit can most effectively be communicated to the consumer in the "Directions for Use" rather than by a container size limitation. The agency believes the Directions "Apply 3 or more sprays not to exceed 10 sprays" is adequate to provide safe use of the product.

References

(1) OTC Volume 160260.
(2) OTC Volume 160266.

II. The Agency's Amended Tentative Adoption of the Panel's Report

A. Summary of Ingredient Categories and Testing of Nonmonograph Conditions

1. *Summary of Ingredient Categories.* The agency has reviewed all the claimed active ingredients submitted to the Panel, as well as other available data and information, and has made the following tentative classification of external analgesic active ingredients for use as male genital desensitizers. As convenience to the reader, the following list is included as a summary of the categorization of active ingredients proposed by the agency.

EXTERNAL ANALGESIC INGREDIENTS FOR USE AS MALE GENITAL DESENSITIZERS

Ingredients	Category	
	Panel	Agency
Benzocaine	I	I
Lidocaine	I	I
Benzyl alcohol	II	II
Ephedrine hydrochloride	II	II
Camphorated metacresol	NA[1]	II

[1] Not applicable.

2. *Testing of nonmonograph conditions.* Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any external analgesic ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740). This policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of the Agency's Changes in the Panel's Recommendations

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the Panel's report and recommended monograph with the changes described in FDA's responses to the comments above and with other changes described in the summary below. A summary of the changes made in the Panel's conclusions and recommendations follows:

1. The agency is not including the limitation on container size for lidocaine recommended by the Panel. (See comment 5 above.)

2. The agency has combined the warning on allergy to benzocaine with the more general warning regarding irritation also included in the advanced notice of proposed rulemaking. (See comment 3 above.)

3. The agency has classified camphorated metacresol as Category II on the basis of a lack of marketing experience or data to support safe and effective use as a male genital desensitizer. (See comment 4 above.)

4. The agency has made further changes in the format and in numbering of the amended tentative final monograph in order to include the amendment in the external analgesic tentative final monograph. (See tentative final monograph below.)

5. Following the format of other documents, the agency has provided for one indication statement to be required and five indications statement to be designated as "other allowable indications." (See tentative final monograph below.)

6. The agency is aware of the Panel's concern about the lack of data on the effect of benzocaine and lidocaine on sperm and the ovum (female egg) (47 FR 39421). Although the Panel's proposed warning statement, "The effect of this product on sperm and fertility has not been determined," is intended to be informative, the agency believes that the warning would not achieve any useful purpose and may even be confusing to consumers.

The agency recognizes that both benzocaine and lidocaine have a long history of topical use with relatively few side effects reported. Benzocaine and lidocaine were reviewed by the Topical Analgesic Panel, which found that the use of benzocaine and lidocaine preparations on the skin, mucous membranes, and internally have been associated with a high degree of safety (44 FR 69793). The Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products reviewed benzocaine for relief of minor vaginal irritations and concluded that benzocaine was safe for intravaginal use. Neither Panel recommended a warning statement such as that proposed by the Miscellaneous External Panel (47 FR 39433). The agency did not receive any comments in favor of or in opposition to this recommendation.

Based on the many years of extensive marketing experience of products containing these ingredients, the recommendations of other advisory panels, and the lack of any data on adverse effects of these drugs on sperm and the ovum, the agency concludes that there is insufficient basis for the

warning and is not including § 348.50(c)(9)(v) in this tentative final monograph.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC external analgesics for use as male genital desensitizers drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Pub. L. 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC external analgesics for use as male genital desensitizers drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC male genital desensitizer drug products. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC male genital desensitizer drug products should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on male genital desensitizer drug products, a period of 120 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 2, 1985, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed regulation. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before January 30, 1986. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests 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. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before October 2, 1986, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before December 2, 1986. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on December 2, 1986. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph is published in the FEDERAL REGISTER, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 348

OTC drugs, External analgesic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended in Part 348 (as proposed in the Federal Register of February 8, 1983 (48 FR 5852)) as follows:

PART 348—EXTERNAL ANALGESIC PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for part 348 continues to read as follows:

Authority: Secs. 201(p) 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); (5 U.S.C. 553), 21 CFR 5.11.

2. In Subpart A, § 343.3 would be amended by adding new paragraph (f), to read as follows:

§ 348.3 Definitions.

* * * * *

(f) *Male genital desensitizing drug product.* A drug product applied to the penis to aid in temporarily slowing the onset of ejaculation.

3. In Subpart B, § 348.10 is amended by adding new paragraph (e), to read as follows:

§ 348.10 Analgesic, anesthetic, and antipruritic active ingredients.

* * * * *

(e) *Male genital desensitizers.* (1) Benzocaine, 3 to 7.5 percent in a water-soluble base.

(2) Lidocaine in a metered spray with approximately 10 milligrams per spray.

4. In Subpart C, § 348.50 is amended by adding new paragraph (a)(3); by revising the introductory text of paragraph (b); by redesignating (b)(4) as (b)(5) and adding new paragraph (b)(4), by adding new paragraph (c)(8), and by redesignating (d) as (d)(1) and adding new paragraph (d)(2), to read as follows:

§ 348.50 Labeling of external analgesic drug products.

(a) * * *

(3) *For products containing any external analgesic ingredient identified in § 348.10(e).* The labeling of the

product contains the established name of the drug, if any, and identifies the product as a "male genital desensitizer."

(b) *Indications.* The labeling of the product states, under the heading "Indication(s)," the following:

* * * * *

(4) *For products containing any ingredient identified in § 348.10(e).* (i) "Aids in the prevention of premature ejaculation."

(ii) *Other allowable indications.* In addition to the information identified in paragraph (b)(4)(i) of this section, the labeling of the product may contain additional indication statements as follows:

(*a*) "For temporary male genital desensitization helping to slow the onset of ejaculation."

(*b*) "Aids in temporarily retarding the onset of ejaculation."

(*c*) "Aids in temporarily slowing the onset of ejaculation."

(*d*) "Aids in temporarily prolonging time until ejaculation."

(*e*) "For reducing oversensitivity in the male in advance of intercourse."

(iii) Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed above, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the prohibitions in section 502(a) of the act against misbranding by the use of false or misleading labeling and the prohibition in section 301(d) of the act against the introduction into interstate commerce of unapproved new drugs.

(c) * * *

(8) *For products containing any ingredient identified in § 348.10(e).* The labeling of the product contains the following warnings under the heading, "Warnings":

(i) "Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor."

(ii) "Avoid contact with the eyes."

(iii) "If you or your partner develop a rash or irritation, such as burning or itching, discontinue use. If symptoms persist, consult a doctor."

(d) * * *

(2) For products containing any ingredient identified in § 348.10(e). The labeling of the product contains the following information under the heading "Directions," followed by "or as directed by a doctor":

(i) *For products containing benzocaine identified in §348.10(e)(1).* "Apply a small amount to head and shaft of penis before intercourse. Wash off after intercourse."

(ii) *For products containing lidocaine identified in § 348.10(e)(2).* "Apply 3 or more sprays, not to exceed 10, to head and shaft of penis before intercourse. Wash off after intercourse."

Dated: May 6, 1985.

Frank E. Young,

Commissioner of Food and Drugs.

Margaret M. Heckler,

Secretary of Health and Human Services.

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