DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 357

[Docket No. 81N-0064]

Deodorant Drug Products for Internal Use for Over-the-Counter Human Use; Tentative Final Monograph

AGENCY: Food and Drug Administration.

ACTION: Notice of Proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking in the form of a tentative final monograph that would establish conditions under which over-the-counter (OTC) deodorant drug products for internal use are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the report and recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and public comments on an advance notice of proposed rulemaking that was based on those recommendations. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objection, or requests for oral hearing on the proposed regulation before the Commissioner of Food and Drugs by August 16, 1985. New data by June 17, 1986. Comments on the new data by August 18, 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 October 15, 1985.

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 January 5, 1982 (47 FR 512) FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC deodorant drug products for internal use, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous Internal Drug Products, which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by April 5, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by May 5, 1982.

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 individuals and one manufacturer submitted comments. Copies of the comments received are on public display in the Docket 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. In this tentative final monograph (proposed rule) to establish Part 357, Subpart I (21 CFR Part 357, Subpart I) FDA states for the first time its position on the establishment of a monograph for OTC deodorant drug products for internal use. 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 deodorant drug products for internal use.

This proposal constitutes FDA's tentative adoption of the Panel's conclusions and recommendations on OTC deodorant drug products for internal use as modified on the basis of the comments received and the agency's independent evaluation of the Panel's report. 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.

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 for OTC deodorant drug products for internal use (published in the **Federal Register** of January 5, 1982; 47 FR 512), the agency suggested that the conditions included in the monograph (Category I) be effective 6 months after the date of publication of the final monograph in the **Federal Register**. Experience has shown that relabeling of products covered by the monograph is necessary in order for manufacturers to comply with the monograph. New labels

containing the monograph labeling have to be written, ordered, received, and incorporated into the manufacturing process. The agency has determined that is is impractical to expect new labeling to be in effect 6 months after the date of publication of the final monograph. Experience has shown also that if the deadline for relabeling is too short, the agency is burdened with extension requests and related paperwork.

In addition, some products may have to be reformulated to comply with the monograph. Reformulation often involves the need to do stability testing on the new product. An accelerated aging process may be used to test a new formulation; however, if the stability testing is not successful, and if further reformulation is required, there could be further delay in having a new product available for manufacture.

The agency wishes to establish a reasonable period of time for relabeling and reformulation in order to avoid an unnecessary disruption of the marketplace that could not only result in economic loss, but also interfere with consumers' access to safe and effective drug products. 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 notice published in the **Federal Register** of November 16, 1973 (38 FR 31696) 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

In its report on OTC deodorant drug products for internal use, the Advisory Review Panel on Miscellaneous Internal Drug Products discussed five basic indications for use for these products: ostomy odor control; fecal incontinence odor control; urinary incontinence odor control; body odor control; and surface lesion odor control. In responding to the comments received on the Panel's report, the agency has organized the issues raised, and the responses, according to the specific indications for use that are addressed.

Although chlorophyllin was used as the name of one of the ingredients evaluated by the Panel, chlorophyllin copper complex is the name for this ingredient adopted by the United States Adopted Names Council (Ref. 1) and is the name used for this ingredient in this tentative final monograph.

Reference

(1) "USAN and the USP Dictionary of Drug Names," 21st Ed., United States Pharmacopeial Convention, Inc., Rockville, MD, p. 104, 1984.

A. Comment on Ostomy Odor Control

1. Two comments supported the safety and effectiveness of bismuth subgallate as a colostomy and ileostomy deodorant and urged that it continue to be available as an OTC drug product. One comment cited 14 years and the other over 17 years of satisfactory personal use of a product containing this ingredient with no ill effects. A third comment, citing 26 years of marketing history, urged the chlorophyllin copper complex be recognized as safe and effective as a colostomy and ileostomy deodorant.

Based on the available data, the Panel concluded that bismuth subgallate and chlorophyllin copper complex are safe for use as oral deodorants, but because of a lack of well-controlled studies in support of effectiveness, the Panel concluded that additional data were necessary to establish their effectiveness.

The agency notes that although proof of effectiveness, as defined in 21 CFR 330.10(a)(4)(ii), shall consist of controlled clinical investigations as defined in 21 CFR 314.126, the regulation also provides for a waiver of this requirement if it can be shown that it is not reasonably applicable to the drug or essential to the validity of the investigation and that an alternative method of investigation is adequate to substantiate effectiveness. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing.

Because the intended effect of these drug products (odor control) is not a therapeutic one, and because odor measurement is at best a subjective measurement by both patients and investigators, the agency believes that the methods of investigation employed in the studies submitted to the Panel and the results obtained (Refs. 1, 2, and 4 through 13), along with the reports of significant human experience during marketing (Refs. 3 and 14) justify a waiver of the well-controlled study requirement.

The data for bismuth subgallate consist of one double-blind, placebo-controlled study in ileostomy patients (Ref. 1) and one uncontrolled study in both colostomy and ileostomy patients (Ref. 2). Both studies showed that the use of bismuth subgallate results in improvement in odors. In addition, reports of 20 years of successful use of this ingredient by members of the United Ostomy Association (Ref. 3) indicate that this ingredient has had long-term use with widespread patient acceptance.

Studies on chlorophyllin copper complex for control of ostomy odors consist of three uncontrolled studies (Refs. 4, 5, and 6) that report consistent results in significant improvement in odor control in both colostomy and ileostomy patients. These data are further supported by a number of additional uncontrolled studies (Refs. 7 through 13) that report consistent significant improvement in odor control in patients with fecal and urinary incontinence who use chlorophyllin copper complex. In addition, this ingredient had been in use for over 25 years with reports of widspread patient acceptance (Ref. 14).

The agency concludes that bismuth subgallate and chlorophyllin copper complex are generally recognized as safe and effective for OTC use in controlling ostomy odors. Based on the doses used in the studies cited above and on doses currently promoted for marketed products, the agency is proposing the following oral dosages: bismuth subgallate 200 to 400 milligrams (mg) up to four times daily; chlorophyllin copper complex 100 to 200 mg daily.

Activated charcoal, the third ingredient reviewed by the Panel for use in controlling ostomy odors, lacks both the amount and quality of data, as well as the history of use and marketing experience of bismuth subgallate or chlorophyllin copper complex. Therefore, activated charcoal has been retained in Category III for ostomy odor control.

References

(1) Sparberg, M., "Bismuth as an Effective Means for the Control of Ileostomy Odor, A Double-Blind Study," *Gastroenterology*, 66:476, 1974.

(2) Goldsmith, M., and N. Gill, unpublished study in OTC Volume 170172, Docket No. 81N–0064, Dockets Management Branch.

(3) Binder, D.P., Executive Director, United Ostomy Association, Inc., "Testimony on Oral Deodorants Ostomates," July 21, 1979, in OTC Volume 17PPAI, Docket No. 81N–0064, Dockets Management Branch.

(4) Weingarten, M., and B. Payson, "Deodorization of Colostomies with Chlorophyll," *The Review of Gastroenterology*, 18:602–604, 1951.

(5) Golden, T., and J.F. Burke, "Effective Management of Offensive Odors," *Gastroenterology*, 31:260–265, 1956.

(6) Siegel, L.H., "The Control of Ileostomy and Colostomy Odors," *Gastroenterology*, 38:634–636, 1960.

(7) Young, R.W., and J.S. Beregi, Jr., "Use of Chlorophyllin in the Care of Geriatric Patients," *Journal of the American Geriatrics Society*, 28:46–47, 1980.

(8) Joseph, M., "The Control of Fecal Odors with Chlorophyll Tablets," *Western Journal of Surgery, Obstetrics and Gynecology*, 60:363–364, 1952.

(9) Morrison, J.E., "Oral Tablets Help Control Ward Odors, Study Shows," *Hospital*, 33:97, 1959.

(10) Laitner, W., "Odor Control in the Incontinent Mental Patient," *Psychiatric Quarterly* (Supplement 2), 29:190–192, 1955.

(11) O'Connell, J., "A Useful Adjunct for Odor Control in Malodorous Surface Lesions and Incontinence," *Journal of the Central Islip State Hospital*, 1:23–26, 1968.

(12) Dory, A.E., "The Control of Odor in Urinary Incontinence," *Nursing Homes*, 20:28, 1971.

(13) Noonan, L., "Summary of Derifil Tablets Trial," unpublished study, Rockland State Hospital, Orangeburg, NY, April 1972 contained in OTC Volume 170014 (Exhibit Y), Docket No. 81N–0064, Dockets Management Branch.

(14) Comment No. C0003, Docket No. 81N–0064, Dockets Management Branch.

B. Comments on Fecal and Urinary Incontinence Odor Control

2. One comment urged that chlorophyllin copper complex be generally recognized as safe and effective for the reduction of fecal or urinary odor associated with incontenence in senile and mental patients in addition to its use in ostomy odor control. In light of a 26-year marketing history of chlorophyllin copper complex for the control of odors associated with incontinence, the comment objected to the Panel's placement of this ingredient in Category III for this claim and to the recommendation for two additional randomized, double-blind, placebo-controlled crossover clinical studies to prove effectiveness. The comment argued that it is unreasonable to require expensive new studies that might be less productive of valid data than the already reported long-term experience of competent practicing professionals in hospitals, institutions, and nursing homes. In addition to citing the favorable results noted in five uncontrolled and/or unblinded studies reviewed by the Panel (Refs. 1 through 5), the comment submitted a 6-month unblinded and uncontrolled study by Young and Beregi (Ref. 6) in which successful results for the control of urinary and fecal odors were estimated to be at least 85 percent. The comment also submitted the results of two questionnaires (Ref. 7). The first questionnaire, mailed to 110 nursing homes which had purchased a chlorophyllin copper complex deodorant, resulted in 35 responses with 34 listing the product as either satisfactory or very satisfactory on a 3-point scale of unsatisfactory, satisfactory or very satisfactory. The second questionnaire, mailed to an unknown number of physicians who had requested and received samples of this same product, resulted in 65 responses listing the product as satisfactory or very satisfactory. The comment also submitted 10 testimonial letters dated between 1964 and 1981 from satisfied users of this chlorophyllin copper complex deodorant.

For the same reasons discussed in the preceding comment, the agency believes that a waiver of the well-controlled study requirement is justified for chlorophyllin copper complex for use in control of odor due to urinary or fecal incontinence. The agency concludes that the studies reviewed by the Panel and cited by the comment, as well as the reports of significant human experience during marketing are adequate to support the claims of odor control for fecal and urinary incontinence. Therefore, the agency is proposing in this tentative final monograph the claim of "an aid to reduce fecal or urinary odor due to incontinence" for chlorophyllin copper complex when used in the dosage range of 100 to 200 mg daily.

References

(1) Dory, A.E., "The Control of Odor in Urinary Incontinence," *Nursing Homes*, 20:28, 1971.

(2) Joseph, M., "The Control of Fecal Odors with Chlorophyll Tables," *Western Journal of Surgery, Obstetrics and Gynecology*, 60:363–364, 1952.

(3) Laitner, W., "Odor Control in the Incontinent Mental Patient," *Psychiatric Quarterly* (Supplement 2), 29:190–192, 1955.

(4) Morrison, J.E., "Oral Tablets Help Control Ward Odors, Study Shows," *Hospital*, 33:97, 1959.

(5) O'Connell, J., "A Useful Adjunct for Odor Control in Malodorous Surface Lesions and Incontinence," *Journal of the Central Islip State Hosptial*, 1:23–60, 1968.

(6) Young, R.W., and J.S. Beregi, Jr., "Use of Chlorophyllin in the Care of Geriatric Patients," *Journal of the American Geriatrics Society*, 28:46–47, 1980.

(7) Comment C0003, Docket No. 81N–0064, Dockets Management Branch.

C. Comment on Body and Surface Lesion Odor Control

3. A comment requested that the recommended Category III labeling claim for chlorophyllin copper complex, "To reduce body (perspiration) odor or surface lesion odor," be expanded to permit the alternative claims, "to reduce breath and body odors not related to faulty hygiene" and "to reduce surface lesion odor." The comment argued that abnormal body odors are not always exuded in perspiration, but sometimes just seem to become part of the flesh, or are excreted by the lungs as breath odors.

The agency does not agree that breath odor claims should be included in Category III for orally ingested chlorophyllin copper complex. Although there were some limited data submitted regarding the systemic use of chlorophyllin copper complex for body odor or surface lesion odor, no data were presented to the Panel or submitted by the comment dealing with the systemic effects of this ingredient on breath odors excreted by the lungs. Therefore, breath odor claims for orally ingested chlorophyllin copper complex remains in Category II in this rulemaking.

The agency recognizes that chlorophyllin copper complex is often added to chewing gum, lozenges, mouthwashes, etc., for its local effect in reducing breath odor. However, the local effect of chlorophyllin copper complex is considered a cosmetic rather than a drug effect and is not subject to this rulemaking.

D. General Comments

4. A comment maintained that the statement recommended in § 357.850(c), "this product cannot be expected to be effective in the reduction of odor due to faulty personal hygiene" is confusing and misleading considering that a patient who is incontinent of urine or feces is certainly guilty of faulty personal hygiene.

This statement was intended by the Panel to caution colostomy and ileostomy patients that these products are not a substitute for the personal hygiene measures normally required in these conditions. However, the agency agrees with the comment that the statement may be confusing and misleading. Therefore, it has not been

proposed in this tentative final monograph.

5. A comment noted that the Panel recommended a warning statement regarding accidental overdose in accordance with § 330.1(g) of the regulations (47 FR 514). The comment requested that this warning be deleted from the labeling requirements for chlorophyllin copper complex deodorants because "no toxicity has been demonstrated for chlorophyllin copper complex administered orally in 26 years of marketing experience."

The Panel noted that chlorophyllin copper complex has extremely low potential for toxicity from accidental overdose. The median lethal dose (LD_{50}) for oral ingestion of a 15-percent aqueous solution of chlorophyllin copper complex for mice was found to be 7 grams per kilogram (g/kg) of body weight. No toxic effects were found in rats from long-term feeding of a diet containing a 3-percent concentration of chlorophyllin copper complex (Ref. 1).

Therefore, FDA is proposing in this tentative final monograph to exempt OTC oral deodorant drug products containing chlorophyllin copper complex from the warning in § 330.1(g) (21 CFR 330.1(g)) that states "In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately."

Reference

(1) Harrison, J.W.E., S.E. Levin, and B. Trabin, "The Safety and Fate of Potassium Sodium Copper Chlorophyllin and Other Copper Compounds" *Journal of American Pharmaceutical Association*, 43:722–737, 1954.

II. The Agency's 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 claimed active ingredients submitted to the Panel, as well as other data and information available at this time and has proposed the recategorization of bismuth subgallate and chlorophyllin copper complex from Category III to Category I for use as OTC internal deodorant active ingredients. For the convenience of the reader, the following table is included as a summary of the categorization of OTC deodorant drug products for internal use active ingredients.

Internal deodorant active ingredient	Panel	Agency
Bismuth subgallate	III	I
Charcoal, activated	III	III
Chlorophyllin copper complex	III	I

The agency is not aware of any data demonstrating the safety and effectiveness of any ingredients not listed above when used as OTC deodorant drug products for internal use. Therefore, the agency is proposing all other ingredients as Category II for this use.

2. *Testing of nonmonograph conditions.* The Panel recommended testing guidelines for OTC deodorant drug products for internal use (47 FR 518). The agency is offering these guidelines as the Panel's recommendations without adopting them or making any formal comment on them. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any internal deodorant 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) and clarified April 1, 1983 (48 FR 14050). That 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 by the agency is as follows:

1. The agency has reclassified bismuth subgallate as safe and effective for ostomy odor control at a dose of 200 to 400 mg up to 4 times daily. (See comment 1 above.)

2. The agency has reclassified chlorophyllin copper complex as safe and effective for ostomy odor control and for fecal and urinary incontinence odor control at a dose of 100 to 200 mg daily. (See comments 1 and 2 above.)

3. The agency has not included in this tentative final monograph, the statement in recommended § 357.850(c), "This product cannot be expected to be effective in the reduction of odor due to faulty personal hygiene." (See comment 4 above.)

4. The agency has exempted chlorophyllin copper complex from the general warning regarding accidental overdose required by § 330.1(g) of the regulations. (See comment 5 above.)

5. The agency has included the term "a colostomy or ileostomy deodorant" as an optional statement of identity rather than as an indication because the wording of this phrase is properly that of a statement of identity.

6. In an effort to simplify OTC drug labeling, the agency proposed in a number of tentative final monographs to substitute the word "doctor" for "physician" in OTC drug monographs on the basis that the word "doctor" is more commonly used and better understood by consumers. Based on comments received to these proposals, the agency has determined that final monographs and other applicable OTC drug regulations will give manufacturers the option of using either the word "physician" or the word "doctor." This tentative final monograph proposes that option.

7. The agency has added the term "incontinence" to the definitions in § 357.803 of this tentative final monograph for the sake of clarity.

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 deodorant drug products for internal use, 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 deodorant drug products for internal use is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have significant economic impact on a substantial number of small entities.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC deodorant drug products for internal use. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by October 15, 1985. 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 that 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.

Exclusivity of Labeling

In the **Federal Register** of April 22, 1985 (50 FR 15810), the agency proposed to change its "exclusivity" policy for the labeling of OTC drug products that has existed during the course of the OTC drug review. Under this policy, 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.

The proposed rule would establish three alternatives for stating the indications for use in OTC drug labeling while all other aspects of OTC drug labeling (i.e., statement of identity, warnings, and directions for use) would continue to be subject to the existing exclusivity policy. The proposed rule for OTC deodorant drug products for internal use included in this document incorporates the exclusivity proposal by providing for the use of other truthful or nonmisleading statements in the product's labeling to describe the indications for use. After considering all comments submitted on the proposed revision to the exclusivity rule, the agency will announce its final decision on this matter in a future issue of the **Federal Register**. The final rule for OTC deodorant drug products for internal use will incorporate the final decision on exclusivity of labeling.

Interested persons may, on or before August 16, 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 October 15, 1985. 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 June 17, 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 August 18, 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 August 18, 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 357

OTC drugs; Anthelmintic drug products, Cholecystokinetic drug products, Deodorant drug products for *internal use, Orally administered drug* products for fever blisters, Poison treatment drug products, and Smoking deterrent 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 357 by adding new Subpart I to read as follows:

PART 357—MISCELLANEOUS INTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

* * * * *

Subpart I—Deodorant Drug Products for Internal Use

Sec.

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.

Subpart I—Deodorant Drug Products for Internal Use

§ 357.801 Scope.

(a) An over-the-counter deodorant drug product for internal use in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this subpart and each general condition established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

§ 357.803 Definitions.

As used in this subpart:

(a) *Colostomy.* An external operative opening of the colon.

(b) *Deodorant for internal use.* An ingredient taken internally to render offensive odors less perceptible.

(c) *Ileostomy.* An external operative opening from the ileum.

(d) *Incontinence.* An inability to retain urine or feces.

§ 357.810 Active ingredients for deodorant drug products for internal use.

The active ingredient of the product consists of either of the following when used within the dosage limits *established for each ingredient in* § 357.850(d):

(a) *Bismuth subgallate.*

(b) *Chlorophyllin copper complex.*

§ 357.850 Labeling of deodorant drug products for internal use.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "deodorant for internal use" or as a "colostomy or ileostomy deodorant."

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

(1) *For products containing bismuth subgallate identified in § 357.810(a).* "An aid to reduce odor from colostomies or ileostomies."

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* (i) "An aid to reduce odor from colostomies or ileostomies."

(ii) "An aid to reduce fecal or urinary odor due to incontinence."

(3) 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) *Warnings.* The warning required by § 330.1(g) concerning overdose is not required on products containing chlorophyllin copper complex identified in § 357.810(b).

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions."

(1) *For products containing bismuth subgallate identified in § 357.810(a).* Adults and children 12 years of age and over: Oral dosage is 200 to 400 milligrams up to 4 times daily. Children under 12 years of age: Consult a doctor.

(2) *For products containing chlorophyllin copper complex identified in § 357.810(b).* Adults and children 12 years of age and over: Oral dosage is 100 to 200 milligrams daily. Children under 12 years of age: Consult a doctor.

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

Frank E. Young,

Commissioner of Food and Drugs.

Dated: May 6, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

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