DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 330, 331, 332, and 357

[Docket No. 82N-0154]

Labeling of Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration.

ACTION: Proposal.

SUMMARY: The Food and Drug Administration (FDA) is proposing to change its "exclusivity" policy for the labeling of over-the-counter (OTC) drug products. The label and labeling of OTC drug products would be required to contain in a prominent and conspicuous location either (1) within a boxed area designated "APPROVED USES" the specific wording on indications for use established under an OTC drug monograph; (2) within a nonboxed area other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling; or (3) within a boxed area designated "APPROVED USES" the approved monograph language plus elsewhere in the labeling alternative language describing indications for use that was not false or misleading. All required OTC drug labeling other than indications (e.g., warnings and directions) would continue to be subject to the existing exclusivity standard. FDA is issuing this proposal after considering testimony and comments submitted during a public hearing on this matter.

DATE: Written comments by July 22, 1985.

ADDRESS: Written comments 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 July 2, 1982 (47 FR 29002), FDA announced a public hearing to be held on the "exclusivity" policy as it relates to the labeling of OTC drugs. This policy currently limits the terms that may be used in an OTC drug product's labeling to the specific terminology established in a final OTC drug monograph.

The hearing, which was held on September 29, 1982, was requested following publication of the tentative final monograph (proposed regulation) for OTC nighttime sleep-aid and stimulant drug products in the **Federal Register** of June 13, 1978 (43 FR 25544). The tentative final monograph for nighttime sleep-aid drug products stated that the labeled indications for such products "shall be limited to one or more of the following phrases: 'Helps fall asleep,' 'For relief of occasional sleeplessness,' 'Helps to reduce difficulty in falling asleep,' " The tentative final monograph for stimulant drug products stated that the labeled indication for such products "shall be limited to the following phrase: 'Helps restore mental alertness or wakefulness when experiencing fatigue or drowsiness.' " The tentative final monograph proposed to exclude all other claims or representations of indications. Moreover, in accordance with FDA's exclusivity policy, the claims and representations would be required to be stated in OTC drug labeling by using only the precise phrases listed above. Thus, when the applicable final monograph became effective, any OTC nighttime sleep-aid or stimulant drug product containing labeling with claims or representations other than those established in the monograph, or using differing terminology, would have been a new drug and/or misbranded under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p) and 352).

I. The Existing Exclusivity Policy

The policy of limiting monograph labeling terminology to specific words and phrases considered and approved by FDA has been the subject of comment throughout the OTC drug review process. With the publication of the tentative final monograph for OTC antacid drug products in the **Federal Register** of November 12, 1973 (38 FR 31260), FDA responded to comments proposing that terms other than those specified in the monograph should be allowed in the product labeling. The agency concluded that the terms recommended by the panel fully met the intent of the regulation. The agency also stated that allowing each manufacturer to select words other than those set forth in the monograph would result in continued consumer confusion and deception (38 FR 31264).

However, in the "Indications" section of the antacid tentative final monograph, FDA proposed as a requirement that the drug products have labeling that "represents or suggests" the product for the allowed antacid indications (38 FR 31268). The "represents or suggests" language was retained when the final monograph for OTC antacid drug products was published in the **Federal Register** of June 4, 1974 (39 FR 19862, 19876).

In the **Federal Register** of March 13, 1975 (40 FR 11718), however, FDA amended the monographs for OTC antacid and antiflatulent drug products. The "represents or suggests" language that had been in the "Indications" section was replaced with a requirement that the "Indications" section contain a statement "that is limited" to the words and phrases set out in quotation marks in the respective monographs. The change was made in response to a comment inquiring whether the phrase "represents or suggests" meant that terms analogous or similar to the quoted conditions could be used.

The change was intended to clarify the agency's position on the exclusivity policy. The controversy concerning exclusivity did not abate, however, even though in subsequent tentative final monographs FDA consistently expanded the labeling recommended by the panels to include alternate terminology suggested in comments.

Subsequently, comments both supporting and objecting to the exclusivity policy were submitted to a number of OTC drug rulemaking proceedings, including the proposed monographs for OTC nighttime sleep-aid and stimulant drug products. The comments objecting to the limitation on labeling terminology asserted that it is unduly restrictive, unconstitutional, and contrary to the purpose of the Federal Food, Drug, and Cosmetic Act. These comments stated that the policy prevents manufacturers from using "truthful alternative wording." In the tentative final monographs for OTC nighttime sleep-aid and stimulant drug products, FDA responded to the comments by reasserting its position on exclusivity (43 FR 25553).

The agency also stated, in a response to a comment on the exclusivity policy as it relates to both nighttime sleep-aid and stimulant drug products, that the agency would permit truthful alternative terminology only after approval of an appropriate petition to the agency under § 330.10(a)(12) (21 CFR 330.10(a)(12)) and publication of an amendment to an appropriate monograph (43 FR 25545).

II. The Public Hearing on the Exclusivity Policy

The objections to the exclusivity policy were resubmitted with respect to nighttime sleep-aid and stimulant drug products after publication of the tentative final monographs for these products, and an oral hearing was requested. In granting the hearing

request, FDA stated that the frequency with which the issue of exclusivity has been raised, and is likely to be raised again with respect to future monographs, justified a hearing to consider whether the agency's long-stated policy on labeling exclusivity for OTC drugs should be retained, modified, or eliminated (47 FR 29003):

In addition, when the agency initiated a retrospective review of its regulations to minimize unnecessary regulatory burdens, as part of the agency's response to Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354) (46 FR 36332, July 14, 1981; 47 FR 29004, July 2, 1982) the exclusivity policy was identified by comments as one that could be made more flexible without sacrificing public health objectives.

A. Scope of the Hearing

The notice of hearing defined the scope of the hearing broadly as encompassing all aspects, both practical and legal, of the exclusivity policy and its possible alternatives. Participants were invited to comment on any matter related to that policy. The inquiry was structured, however, to seek answers to the following questions (47 FR 29003):

(1) Does the government have a substantial interest in restricting the terminology used in the labeling of OTC drug products?

(2) If the government's interest is substantial, does restricting labeling to terminology approved by FDA in a final monograph directly advance this interest?

(3) Is the restriction imposed by the exclusivity policy more extensive than is necessary to serve that interest?

(4) By imposing such a restriction, does the agency exceed its authority under the Federal Food, Drug, and Cosmetic Act?

(5) Is the restriction a prior restraint on free speech that is prohibited by the Constitution?

(6) Should there be limitations on terminology used in the labeling of OTC drug products? If the current policy of exclusivity of labeling should be changed, what changes would be desirable from the standpoint of consumers and marketers?

B. Alternatives Explored at the Hearing

The notice of hearing identified and solicited comments on the following possible alternatives to the exclusivity policy:

(1) Provide a separate list of approved synonyms maintained on file in the Dockets Management Branch.

The notice stated that this alternative would retain the exclusivity policy but provide a simpler and more expeditious means of obtaining additional acceptable language for use in labeling.

(2) Require specific information to be included in a designated area of a product's labeling without deviation from the approved language but permit manufacturers to use their own synonymous language outside the designated area.

The notice stated that this alternative would preserve the exclusivity policy with respect to claims made in the designated area, thus providing consumers with an FDA-approved source of information on the label itself, while at the same time allowing manufacturers the flexibility to employ reasonable truthful interpretative language elsewhere in the product's labeling. The notice also stated that the agency believed that this alternative represents a compromise that may incorporate the advantages of the exclusivity policy while avoiding some of its perceived rigidity.

(3) Allow manufacturers to interpret the claims included in a monograph in synonymous language.

The notice stated that this alternative would abandon the exclusivity policy. Manufacturers would still be required to employ accurate, nonmisleading terminology, but would not have to obtain FDA's prior approval for the language chosen.

At the hearing on September 29, 1982, 12 persons presented testimony on behalf of manufacturers, trade associations, and consumers. Written testimony was submitted by individuals, companies, and organizations. Comments and testimony by manufacturers and trade associations contended that the present exclusivity policy is unconstitutional because it unlawfuly restrains free speech; is in violation of the Administrative Procedure Act (APA) because it was implemented without notice and comment and because it is arbitrary and capricious; and is not authorized by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.). These comments also questioned whether, as a matter of sound agency policy, FDA should continue the policy irrespective of its legal status. In general, testimony and comments submitted by individuals or consumer groups urged FDA to retain the exclusivity policy in its present form to avoid confusion and deception and to facilitate comparisons among products. In its testimony, the American Association of Retired Persons (AARP) took the position that while it is important that limitations be placed on labeling so as to avoid confusion, alternative wording of labeling claims could also be advantageous.

III. Proposed Change

The agency has decided, after consideration of the testimony and information submitted at the hearing and the comments submitted in the various proceedings to establish OTC drug monographs, that the present exclusivity policy, while legally supportable, should not be continued for policy reasons. FDA specifically rejects the assertions in the submitted comments that the present policy is legally deficient on constitutional grounds, is in violation of the Administrative Procedure Act (APA), or contrary to the Federal Food, Drug, and Cosmetic Act.

The present policy clearly falls within restraints on commercial speech allowed by the Supreme Court in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748 (1976); *Central Hudson Gas & Electric Corp.* v. *Public Service Comm'n*, 447 U.S. 557 (1980); and *Matter of R.M.J.*, 455 U.S. 191 (1982). The policy also meets the requirements of the APA both with respect to the requirement of notice and the standards of arbitrary and capricious agency action. Finally, the present policy is well within the scope of activities authorized by the Federal Food, Drug, and Cosmetic Act. Section 701(a) of the act (21 U.S.C. 371(a)) provides that the agency may "promulgate regulations for the efficient enforcement of this Act." Although there have been many challenges to FDA regulations promulgated under section 701(a), the courts have, with few exceptions, upheld FDA's authority to issue the regulation in question. See, for example, *Toilet Goods Ass'n* v. *Gardner*, 387 U.S. 158 (1967). See also, *National Confectioners Ass'n* v. *Califano*, 569 F.2d 690, 693 (D.C. Cir. 1978); *Cosmetic, Toiletry & Fragrance Ass'n* v. *Schmidt*, 409 F. Supp. 57 (D.D.C. 1976).

In sum, the agency believes that the exclusivity policy is lawful under the Constitution, the APA, and the act. However, even though the agency believes that the exclusivity policy as presently constituted is lawful, there are sound reasons for proposing a modification of that policy.

The agency's principal purpose in establishing and maintaining the exclusivity policy has been to ensure that OTC drug labeling is clear, accurate, and meaningful to the consumer. In the past, the agency has been concerned that unless the policy is rigidly adhered to, there is potential for labeling to be used that is misleading or confusing. The agency's basic premise has not changed. After careful review

and study, however, the agency now believes that the goal of ensuring truthful, nonmisleading labeling without inhibiting effective consumer communication does not require the enforcement of a rigid exclusivity policy. Recognizing that, within limits, there can be various ways of accurately stating the same thing, some of which may even be more meaningful to potential purchasers of OTC drug products, the agency has concluded that it can meet its responsibilities by providing greater flexibility for the use of alternative truthful statements without recourse to the time and resource consuming monograph amendment process. Rather, the agency will use the monograph language as its standard in determining whether alternative statements are accurate or require regulatory action, thus achieving its goals at a lower cost in terms of administrative and enforcement resources.

As discussed in detail below, the new labeling requirements would allow for a alternative labeling of OTC drug products. The label and labeling would be required to contain, in a prominent and conspicuous location, either (1) within a boxed area that is designated "APPROVED USES" the specific wording set out in the indications for use section of an applicable OTC drug monograph, or (2) within a nonboxed area alternative wording relating to indications for use that is not false or misleading. As a third alternative, monograph lanugage would be used in the boxed area and the label and labeling could contain elsewhere alternative wording describing indications for use, so long as the alternative wording was not false or misleading.

The agency believes that labeling established in an OTC drug monograph would continue to serve a vital purpose. It would represent the agency's determination, following extensive notice and comment rulemaking, of the specific indications for which an OTC drug product would be generally recognized as safe and effective, and not misbranded. Because the monographs would provide a definitive explanation of those uses a particular drug is good for, FDA would be able to determine whether nonmonograph language is an accurate description of a drug's properties. Having made such a determination, the agency is in a much better position of determining appropriate regulatory action than it would be, or was, in a nonmonograph situation. While other wording may be developed that would also meet these criteria, the specific wording established in the monograph would provide a standard for measuring the accuracy of synonymous terminology. The standard could be used both by the agency in determining appropriate enforcement actions and by the courts in evaluating the merits of such actions.

The agency emphasizes, as described below in the discussion of the proposed regulation, that it will use the monograph language as a regulatory benchmark. FDA will carefully examine any alternative language to ensure that it does not go beyond the approved indications, thereby causing the drug to become a "new drug" or misbranded, or both, under the act. Language that is so nondescriptive as to be meaningless, or that indicates uses for a new indication, would cause the product to be misbranded, a new drug, or both.

The agency also believes that a change in policy will save resources, with no loss in consumer protection. Under the present exclusivity policy, changes to labeling established in a final monograph may be made only by amending the final monograph (21 CFR 330.10(a)(12)). FDA on its own initiative may propose to amend a monograph, or any interested person may petition FDA for an amendment under 21 CFR 10.30. In accordance with the APA and FDA's own regulations, before an amendment can become final, FDA must determine that there is adequate evidence to propose the amendment in terms of safety, effectiveness, and compliance with the act's misbranding provisions. The amendment then is published as a proposal in the **Federal Register**, and interested persons are provided an opportunity to comment. Following consideration of any comments received and other material in the record, if FDA determines that the amendment should be made, a final regulation is published in the **Federal Register.**

Amendment petitions filed with the agency to date, as well as comments submitted regarding the exclusivity policy, indicate that the principal objection to the policy is that it limits truthful alternate language, not that language included in the monograph is deficient. In sum, more terms are sought to describe a product's indications for use. Moreover, many of the terms sought are suitable candidates for inclusion in the monograph; they comport with the act's requirements with respect to false and misleading labeling.

Under the circumstances, the agency believes that it is no longer a sound use of resources to enforce the exclusivity policy as it relates to indications for use. FDA believes that many words that would trigger an FDA enforcement action because they were not included in a final monograph may subsequently be determined by FDA to be valid under the present monograph amendment process. Moreover, there is little justification for maintaining a review system that can accommodate large numbers of petitions for amendment on a timely basis, because frequently a petitioner seeks only to have words added to the monograph that could not in any practical sense be regarded as affecting the consumer's understanding of the intended uses for which the product has been found safe and effective. The agency believes that the original objectives of the OTC drug review can be met by requiring labeling describing indications for use that has been developed during the monograph process, or truthful, nonmisleading alternative language, subject to the prohibitions in 21 U.S.C. 352(a) against false or misleading labeling, to be displayed in a prominent and conspicuous manner at time of purchase and use in an OTC drug product's label and labeling.

However, FDA emphasizes that the relaxation of the exclusivity policy would apply only to indications for use that are established in a final monograph. As discussed below, all other required OTC drug labeling would continue to be subject to the existing exclusivity standard.

IV. Proposed Regulation

Accordingly, FDA is proposing to amend the labeling requirements for OTC drugs in 21 CFR Part 330 by amending § 330.1. As amended, this section would establish three ways of stating the indications for use in OTC drug labeling. The first would require that the label and labeling for OTC drug products contain in a prominent and conspicuous location that is easily read at time of purchase and use the terminology describing the indications for use that have been established in an applicable final monograph. The terminology would be required to consist of the exact language of the monograph. This terminology would appear within a boxed area designated "APPROVED USES" each time it appears, as appropriate, in the labeling, e.g., on the outer carton, inner bottle label, and in any package insert. Other OTC labeling requirements established under 21 CFR Subchapter C and Subchapter D (21 CFR Parts 200 and 300) could, at the manufacturer's discretion, also appear within the boxed area. In such case, the boxed area would be designated "APPROVED INFORMATION," rather than

"APPROVED USES." A statement that the information in the box was published by the Food and Drug Adminstration would appear either within the boxed area or reasonably close by. In lieu of such statement, manufacturers would have the option of modifying the designation of the boxed area to read "FDA APPROVED USES" or "FDA APPROVED INFORMATION," as appropriate, or "USES (or "INFORMATION") APPROVED BY THE FOOD AND DRUG ADMINISTRATION," or other similar wording.

A manufacturer that elects to use the exact wording of the monograph would be assured that FDA agrees that such labeling is appropriate. Moreover, the manufacturer would be allowed to state that such language has been approved by FDA. The agency anticipates that consumers will look for the approved labeling when purchasing OTC drugs, thereby providing an incentive for manufacturers to use this alternative.

The second alternative way of stating the indications for use would be to use, in a prominent and conspicuous place in the labeling, other truthful and nonmisleading language describing those indications for use that have been developed under a relevant monograph, subject to the prohibition in the act against false or misleading labeling. However, such alternative terminology could not be boxed and could not contain the "APPROVED USES" or "APPROVED INFORMATION" designation or any statement asserting or implying that the indication statement appearing in the prominent and conspicuous area was published by the Food and Drug Adminstration.

As a third alternative, monograph language could be used in the boxed area (the first alternative, discussed above) and other truthful and nonmisleading alternative language describing those indications for use that have been developed under a relevant monograph could appear elsewhere in the labeling, subject to the prohibition in the act against false or misleading labeling.

It is emphasized that any alternative language describing an indication for use that has been established in a relevant final monograph could not be inconsistent with that indication for use or imply or indicate a use that is not established under a relevant monograph. Alternative language representing or suggesting that the drug is safe and effective for some indication for use other than those established in an appropriate final monograph would render the drug product a "new drug" under 21 U.S.C. 321(p) for which an approved new drug application would be required under 21 U.S.C. 335.

A number of tentative final monographs published recently have contained proposed supplemental language relating to indications. These statements have been listed in the proposed *Indications* section and have been captioned as *Other allowable indications* or *Other allowable statements*. See, for example, the tentative final monographs for topical otic and topical antimicrobial drug products, published in the **Federal Register** of July 9, 1982 (47 FR 29986, 29999 and 47 FR 30012, 30020); for bronchodilator drug products, published in the **Federal Register** of October 26, 1982 (47 FR 47520, 47527); and for external analgesic drug products, published in the **Federal Register** of February 8, 1983 (48 FR 5852, 5868). As proposed in these tentative final monographs, other allowable statements describing indications would have been permitted on the labeling in addition to the other required information (such as statement of identity, indications, warnings, and directions) provided that the statements were not placed in direct conjuction with the information required to appear in the labeling or did not occupy labeling space with greater prominence or conspicuousness than the required information. In effect, such supplemental information has been tentatively determined by FDA not to be false or misleading when used with the required information. In the context of the present proposal, these statements are examples of other truthful and nonmisleading labeling that would be allowed. While certainly not exhaustive of such terms and while subject to later modification by FDA, the terms are considered to meet the statutory standards relating to false or misleading labeling (21 U.S.C. 352). In the future, although these terms may be developed during the tentative final monograph stage of the OTC drug review, they will not be included in a final monograph. FDA believes that because such terms are only examples of other acceptable language, their inclusion in a final monograph would not be useful.

The provisions of the regulations relating to the amendment of monographs (§ 330.10(1)(12)) would not be affected by this proposal. Persons seeking to amend the language established by a monograph would continue to follow these procedures.

V. Conforming Amendments

FDA is also proposing conforming amendments to the monographs for OTC antacid, antiflatulent, and cholecystokinetic drug products that appear in 21 CFR Parts 331, 332, and 357, respectively. Other conforming amendments, as required, may be made to other monographs as they are published in final form.

The agency has examined the economic consequences of this proposed rulemaking and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96-354).

Absent special circumstance that would justify reducing the time interval, manufacturers would have up to 12 months after each final monograph is published in the **Federal Register** to revise their product labeling. In most cases, this would be routinely done at the next printing so that minimal costs should be incurred. Thus, the impact of the proposed rule, if implemented, appears to be minimal. Therefore, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC drug products. Comments regarding the impact of this rulemaking on OTC drug products should be accompanied by documentation. 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(d)(9) (proposed December 11, 1979; 44 FR 71742) that this proposal is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Parts 330, 331, 332, and 357

OTC drugs, Labeling requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act (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)) and the Administrative Procedure Act (secs. 4, 5, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703

704)) and under 21 CFR 5.11, it is proposed that Parts 330, 331, 332, and 357 be amended as follows:

1. In Part 330, in § 330.1 by redesignating existing paragraph (c) as paragraph (c)(1) and by adding new paragraph (c)(2), to read as follows:

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

§ 330.1 General conditions for general recognition as safe, effective, and not misbranded.

* * * * *

(c)(1) * * *

(2)(i) The label and labeling of the product contain in a prominent and conspicuous location the labeling describing the "Indications" that have been established in an applicable final monograph. This labeling shall appear in a boxed area designated "APPROVED USES" each time it appears, as appropriate, in the labeling, e.g., on the outer carton, inner bottle label, and on any package insert or display placard. Other applicable labeling established under this Subchapter and Subchapter C of this chapter may be included in the boxed area. If such other labeling is included, the boxed area shall be designated "APPROVED INFORMATION" rather than "APPROVED USES." the "Indications" information appearing in the boxed area shall be stated in the exact language of the monograph. Other information within the boxed area also shall be stated in exact language where exact language has been established by an applicable monograph or by regulation. A statement that the information in the box was "published by the Food and Drug Administration" shall appear within the boxed area, or reasonably close by. In lieu of such statement, the designation of the boxed area may be modified to read: "FDA APPROVED USES" or "FDA APPROVED INFORMATION," as appropriate; "USES (or "INFORMATION") APPROVED BY THE FOOD AND DRUG ADMINISTRATION," or other similar wording.

(ii) At the option of the manufacturer, as an alternative to the requirements of paragraph (c)(2)(i) of this section, the label and labeling of the product shall contain in a prominent and conspicuous location these or other truthful and nonmisleading statements describing only those indications for use that have been 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 and the prohibition in section 301(d) of the act against the introduction into interstate commerce of unapproved new drugs. Such labeling may not be boxed and may not contain the statements provided in paragraph (c)(2) (i) of this section relating to "APPROVED USES," "APPROVED INFORMATION," or that the labeling has been published by the Food and Drug Administration.

(iii) At the option of the manufacturer, the label and labeling may meet the requirements of paragraph (c)(2)(i) of this section and, in addition, other truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph may appear elsewhere in the labeling, that is, outside the boxed area, 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.

(iv) The term "prominent and conspicuous location" as used in paragraph (c)(2) (i) and (ii) of this section means that the labeling with the boxed or nonboxed area shall be presented and displayed in such a manner as to render it likely to be read and understood by the ordinary individual under customary conditions at both time of purchase and use.

(v) Regardless of the option selected by the manufacturer to describe indications, paragraphs (c)(2) (i), (ii), and (iii) of this section require other labeling established under this Subchapter and Subchapter C of this chapter to be stated in the exact language of the applicable monograph or regulation.

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

2. In Part 331, in § 331.30 by revising paragraph (b) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the relief of" (optional, any or all of the following:) "heartburn," "sour stomach," and/or "acid indigestion" (which may be followed by the optional statement:) "and upset stomach associated with" (optional, as appropriate) "this symptom" or "these symptoms." 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.

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PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. In Part 332, in § 332.30 by revising paragraph (a) to read as follows:

§ 332.30 Labeling of antiflatulent products.

(a) *Indications.* The labeling of the product states, under the heading "Indications," the following: "antiflatulent" and/or "to alleviate or relieve the symptoms of gas." 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.

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

4. In Part 357, in § 357.250 by revising paragraph (b) to read as follows:

§ 357.250 Labeling of cholecystokinetic drug products.

* * * * *

(b) *Indications.* The labeling of the product states, under the heading "Indications," the following: "For the contraction of the gallbladder during diagnostic gallbladder studies." 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), 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.

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Interested persons may, on or before July 22, 1985 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600

Fishers Lane, Rockville, MD 20857, written comments on the proposed regulation. 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. Comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Frank E. Young,

Commissioner of Food and Drugs.

Dated: March 21, 1985.

Margaret M. Heckler,

Secretary of Health and Human Services.

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