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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule changing its "exclusivity" policy for the labeling of over-the-counter (OTC) drug products. The final rule establishes three alternatives for stating an OTC drug product's indications for use in OTC drug labeling. The label and labeling of OTC drug products are required to contain, in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All required OTC drug labeling other than indications for use (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under an OTC drug monograph. FDA is issuing this final rule after consideration of the comments submitted in response to the agency's proposed rule that was published in the **Federal Register** of April 22, 1985 (50 FR 15810).

EFFECTIVE DATE: June 30, 1986.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 2, 1982 (47 FR 29002), FDA announced a public hearing to be held on the "exlusivity" policy as it relates to the labeling of OTC drug products. 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. Thus, when an applicable final monograph became effective, any OTC 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).

At the hearing on September 29, 1982, 12 persons presented testimony on behalf of manufacturers, trade associations, and consumers. Written testimony ws submitted by individuals, companies, and organizations. Comments and testimony by manufacturers and trade associations contended that the present exclusivity policy is unconstitutional because it unlawfully 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 act (21 U.S.C. 321 et seq.). These comments also questioned whether, as a matter of sound agency 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 OTC drug products. However, testimony from one consumer group 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.

In the **Federal Register** of April 22, 1985 (50 FR 15810), FDA discussed the testimony and information submitted at the hearing and the comments submitted in various proceedings to establish OTC drug monographs. The agency stated that, although the present policy is lawful, there were sound reasons for proposing a modification of that policy. (See 50 FR 15811.) Accordingly, FDA proposed to amend the labeling requirements for OTC drugs in 21 CFR Part 330 by amending § 330.1.

FDA also proposed conforming amendments to the monographs for OTC antacid, antiflatulent, and cholecystokinetic drug products that appear in 21 CFR Parts 331, 332, and 357, respectively. The agency stated that other conforming amendments, as required, may be made to other monographs as they are published in final form. FDA also stated that the provisions of the regulations relating to the amendment of monographs (Section 330.10(a)(12)) would not be affected by the proposed amendment of the exclusivity policy. Persons seeking to amend the language established by a monograph would continue to follow the procedures set out in § 330.10(a)(12).

Interested persons were invited to file written comments regarding the proposal by July 22, 1985. In response to the proposed rule, 54 consumers, 8 manufacturers, 7 health care providers, 9 government agencies, 14 consumer/trade associations, and 1 university submitted comments. Copies of the comments received are on public display in the Dockets Management Branch. Final agency action on this matter occurs with the publication of this final rule.

I. The Agency's Conclusions on the Comments

1. Many of the comments received in support of the proposal to change the existing exclusivity policy were general in nature. Reasons given by these comments for supporting the proposal include the following: The proposal is in the public interest; will meet consumers' needs for accurate labeling information; will improve patients' understanding of OTC drug products; will assist manufacturers in writing clear communications to consumers; will allow manufacturers the opportunity to change label information without complying with unnecessary FDA procedures; will provide for regional differences in the way people refer to the same condition, e.g., acid stomach versus upset stomach; and will provide greater flexibility. Other comments maintained that a revised exclusivity policy would reduce costs, expedite work, and save agency resources by eliminating the costly monograph amendment procedures.

FDA acknowledges these comments in support of the proposed change in the exclusivity policy.

2. A number of comments stated that it is in the consumers' interest to maintain the old exclusivity policy because it assures accurate and uniform labeling of OTC drug products and assists consumers, especially the poor, sick, and elderly, in purchasing OTC drug products through easy comparisons. Reasons given by these comments for maintaining the old policy include the following: Manufacturers cannot be relied upon to provide accurate, nonmisleading label information; a number of products are switching from prescription to OTC marketing status; the manufacturer's choice, consumer interpretation, and differences in regional language would

increase communications problems; it is not apparent that the cost of drugs would be lower because of this proposal. One comment argued that confusion already exists because consumers do not realize the limits of FDA's power and therefore expect more control.

Explaining that panel members had debated many hours for years over the wording that would be appropriate for OTC drug labeling, two former panel chairpersons stated that the panel members were acutely aware that many other words could be used, but that approval should be obtained from a responsible FDA group. The former chairpersons expressed concern that the proposed change in the exclusivity policy could result in the public being misled about an OTC drug product's capability.

The concerns expressed in this comment were discussed in depth in the proposed rule (50 FR 15810) and are also discussed in comment 4 below. After careful review and study, the agency believes that the goal of ensuring truthful, nonmisleading labeling without inhibiting effective consumer communication does not require that the existing rigid exclusivity policy be continued. Specific wording established in a final OTC drug monograph will provide a standard for measuring the accuracy of alternative language developed by manufacturers for the indications of OTC drug products. Language which represents or suggests that the drug is safe and effective for an indication for use other than one established in a appropriate final monograph would render the drug product a "new drug" under 21 U.S.C. 321(p) for which appropriate regulatory action could be taken. The monograph amendment procedures in § 330.10(a)(12) would also continue to apply where a manufacturer seeks approval for other language for indications for use already included in the monograph.

3. Three comments argued that the new policy was a license for manufacturers of OTC drug products to use words that are misleading and confusing. One comment stated that the proposed changes in exclusivity would increase the likelihood that the consumer will be misled. According to the comment, this situation could lead to medical problems, and the taxpayer would ultimately pay for up to 40 percent of the costs of dealing with the problems.

Expressing the opposite point of view, another comment stated that consumers will have more useful information on which they can base their purchase and treatment decisions, and thus are more likely to identify quickly and rely on appropriate and effective OTC drug products rather than on more costly or less efficient alternatives.

The agency finds no evidence to support the contention that flexible labeling of the indications for use of OTC drug products will be misleading, confuse the consumer, and lead to medical problems. As discussed later in this document, the monograph language will continue to be used as a benchmark to ensure that any alternative language does not exceed the approved indications. (See comment 4 below.) FDA will continue to review the labeling of OTC drug products and initiate enforcement activities as necessary, thereby ensuring that consumers will continue to be protected. (See comment 12 below.)

The agency's experience to date provides no basis for the presumption that this change in policy will cause any deterioration in OTC drug product labeling practices because, for the most part, rigid adherence to the strict "exclusivity" policy has not been required in the absence of final OTC drug monographs. The vast majority of OTC drug products are now marketed pursuant to statutory and regulatory standards that will remain in effect upon publication of this final rule. Experience does not demonstrate any significant widespread patterns of abuse, even in the absence of established "exclusivity" provisions, and there is no reason to expect such abuses to emerge under the revised policy.

Regardless of which alternative manufacturers choose, FDA regulations require that the labeling of OTC drug products be clear and truthful in all respects, not false or misleading in any particular, and understandable to the ordinary individual, including individuals of low comprehension, under customary conditions of purchase and use. (See 21 CFR 330.10(a)(4)(v).) FDA believes that allowing alternative terminology for describing indications for use that have been developed under a relevant OTC drug monograph is consistent with the purpose of § 330.10(a)(4)(v).

4. A number of comments contended that approval of the new proposal would result in unfair competition between manufacturers of OTC drug products. One comment contended that the proposal would benefit unscrupulous manufacturers and those who are cleverest at bending the truth, and would be most harmful to competing manufacturers of higher integrity and to unwitting consumers. The comment added that in time bad labels would drive good labels out of the marketplace. A second comment stated that unfair competition will result as companies compete to convince consumers that their products are superior to the products of competitors who abide by FDA's monograph.

Another comment stated that it was not confident that companies involved would be either totally truthful or not misleading in their advertising efforts, and added that an increase in the cost of OTC drugs to cover advertising campaigns is likely to occur. Another comment claimed that many consumers are under the false impression that advertising and labeling claims are approved in advance by FDA. Other comments contended that substitute language could be a sales gimmick or possibly "one-up-manship." According to some comments, if the restrictions on drug labeling are lifted, bolder claims, not validated by testing, will in time appear. The comments assert that if drug companies are allowed to use their own format, the company with the best marketing technique, not necessarily with the best drug for the indication, will be the more successful, and this practice in turn will increase costs to the consumer. One comment added that the new policy would undermine confidence in FDA.

As stated in the proposal (50 FR 15810), 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 was rigidly adhered to, there was potential for labeling to be used that was 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 admininstrative and enforcement resources. However, FDA emphasizes that the relaxation of the exclusivity policy applies only to indications for use that are established in a final monograph; other required OTC drug labeling continues to be subject to the existing exclusivity standard.

FDA intends to carefully examine the labeling of OTC drug products to ensure that any alternative language that manufacturers use does not go beyond the approved indications for use, thereby causing the drug to become a "new drug" or "misbranded" or both under the act. If unacceptable language is discovered, the agency will take appropriate regulatory action. The agency believes that a sound enforcement program will minimize any unfair competition that would otherwise result from improper labeling.

In response to the comment's concern about the new policy causing untruthful or misleading OTC drug advertising, FDA notes that the Federal Trade Commission (FTC) has the primary responsibility for regulating OTC drug advertising, and that both the past "exclusivity" policy and the revised policy would affect advertising only in those circumstances in which it falls under the act's labeling provisions.[1] In addition, existing regulations in § 330.1(d) (21 CFR 330.1(d)) remain in effect and provide that, for an OTC drug to be generally recognized as safe and effective and not misbranded, its advertising may prescribe, recommend, or suggest the drug's use only under the conditions stated in the labeling.

5. Several comments stated a preference for a specific labeling alternative included in the proposal. Three comments expressed particular support of the provisions in the first alternative that permit the listing in OTC drug labeling of the words "APPROVED USES" or "FDA APPROVED USES" provided the monograph language is used. Other comments, however, argued that the agency should delete the first and third alternatives from the proposal and retain only the second alternative (which permits the use of other truthful and nonmisleading language to describe those indications for use that have been developed under a relevant OTC drug monograph), because any policy other than alternative 2 serves no compelling government interest and indeed disserves the public. Another comment commended FDA for its judgments and wisdom in proposing alternative 2. Two comments supported the third alternative, i.e., the use of monograph language in the boxed area (first alternative) and other truthful and nonmisleading alternative language elsewhere in the labeling. One comment stated that the third alternative appears to be the best for both the consumer and the manufacturer, adding that it "gives the consumer the most information and the manufacturer can indicate uses that the consumer did not know the products could be used for."

Three comments requested a hearing if alternative 2 is not selected and implemented as the only provision of the final rule.

Concerning the comments that stated a preference for one alternative or another, the agency reiterates that the purpose of revising the exclusivity policy was to estabish alternative methods of labeling OTC drug products. In particular, the agency disagrees with the comments that contended that only the second labeling alternative should be retained in the final regulation. The agency's reason for changing the exclusivity policy is to make the policy more flexible, not to eliminate entirely the use of specific language developed during the OTC drug review. Moreover, the use of the "FDA Approved" language will enable manufacturers to market OTC drug products knowing that the indications for use are approved by the agency. The availability of this option should enable manufacturers who choose to do so to market OTC drugs without spending time and resources developing alternative language.

The agency does not believe that it would be a disservice to the public, as alleged by some comments, if OTC drug labeling contains a section entitled "APPROVED USES" or "FDA APPROVED USES." The agency believes that some manufacturers and many consumers would favor such information in the labeling of OTC drug products. Many comments made by consumers on the proposal expressed such a view. In response to one comment, the agency also points out that while the third alternative may allow a manufacturer to indicate uses that the consumer was unaware of, such indications for use are limited to those established in an appropriate monograph.

Finally, the requests for a hearing unless only alternative 2 is adopted are denied. The final regulation permits a manufacturer to use only alternative 2 if it so chooses even though other manufacturers may elect to use another alternative. The comments have not raised any new issues appropriate for resolution at another hearing or shown that any policy other than adopting alternative 2 alone would be contrary to the public interest. As described above, the agency has already conducted one hearing on this labeling policy (September 29, 1982). The Commissioner does not believe that a second hearing would yield additional information not already presented at the previous hearing or in the comments on the proposed rule. Accordingly, the requests for a hearing are denied.

6. Several comments stated that the first and third alternatives are "extensions of the exclusivity policy" to the extent that they mandate use of specific language approved by FDA. The comments argued that, as such, the proposed alternatives represent unconstitutional restrictions on first amendment rights to truthful commercial speech; exceed FDA's statutory authority under sections 502, 201(p), and 701(a) of the act (21 U.S.C. 352, 321(p), and 371(a)); are arbitrary and capricious because they are not supported by an adequate administrative record; and are unwise from a public policy standpoint.

One comment referred to a recent case in which the Supreme Court reviewed restrictions on commercial speech by governmental bodies and reiterated its concern for any abridgment of first amendment rights. (*Zauderer* v. *Ohio*,—— U.S.——, 105 S. Ct. 2265 (1985).) The comment contended that *Zauderer* further establishes that the exclusivity policy adopted in 1975 is unconstitutional and that the current proposal, while more flexible, continues to raise constitutional questions that must be considered.

Other than the reference to *Zauderer*, the comments did not raise any constitutional or legal issues concerning the existing policy or the proposed changes that had not previously been discussed in the proposed rule. (See 50 FR 15811.)

The agency believes that the new rule is constitutionally sound. As the comments assert, commercial speech is entitled to the protection of the first amendment. However, as noted in recent Supreme Court cases, reasonable restrictions may be imposed to ensure that commercial speech is not false or deceptive, and other restrictions may also be imposed when there is a legitimate and substantial interest to be achieved. See, for example, *Central Hudson Gas & Electric Corp.* v. *Public Services Commission*, 447 U.S. 557, 564, 566 (1980).

[1] See, e.g., *United States* v. *Article of Drug . . . B-Complex Cholinos Capsules*, 362 F.2d 923 (3d Cir. 1966); *V.E. Irons, Inc.* v. *United States*, 244 F.2d 34 (10th Cir.), cert. denied, 354 U.S. 923 (1957).

The *Zauderer* case cited by the comments concerned the regulation by the State of Ohio of attorney advertisements. The Supreme Court restated the principle that attorney advertisements are commercial speech entitled to first amendment protection and that commercial speech which is not false or deceptive and does not concern unlawful activities may be restricted only where there is a substantial government interest and then only through means directly advancing that interest. *Zauderer, supra* at 2275–2276. The Court then went on to hold that some of the restrictions imposed by the State on the attorney advertisements were unconstitutional while other restrictions were not.

OTC drug labeling is commercial speech with a special public health function. It helps ensure that OTC drugs are used safely and effectively. In cases involving public health and safety, courts have held that additional restrictions on commercial speech may pass constitutional scrutiny. (See *Central Hudson Gas & Electric Corp., supra.*) As pointed out in the preamble to the proposal (50 FR 15811) and discussed above, the agency has concluded that the exclusivity policy adopted in 1975, while legally supportable, should not be continued for policy reasons; the goal of ensuring truthful, non-misleading labeling without inhibiting effective consumer communication does not require continuation of a rigid exclusivity policy.

The new labeling scheme provided for in this rule permits three alternatives, ranging from specific words established by FDA to other truthful and nonmisleading language, subject only to the minimal restrictions that the labeling not be false or misleading. Manufacturers who believe that one of the three alternatives is overly intrusive may select another alternative, including the development of their own alternative statements. The agency believes that the minimal restrictions contained in this rule clearly fall within the constitutional limits for commercial speech generally as set forth in the cases cited by the comments, and well within constitutional limits for commercial speech dealing directly with matters of public health and safety.

7. Referring to the first alternative of the exclusivity proposal, several comments maintained that "FDA APPROVED USES" language should be permitted for OTC drug products marketed under a new drug application (NDA) as well as for those marketed under an OTC drug monograph.

One comment noted that section 301(1) of the act (21 U.S.C. 331(1)) prohibits the use in labeling of any representation or suggestion that "approval of an application with respect to such drug * * * is in effect under section 355 [the new drug approval provision] * * *." The comment argued that the use of the "FDA APPROVED" language is contrary to the intent and meaning of section 301(1). The comment stated that as a result non-NDA'd OTC drug products would be allowed to use such language, but that NDA'd OTC drug products would be prohibited from using it. The comment maintained that the issue of labeling NDA'd OTC drugs as "FDA APPROVED" could only be adequately resolved legislatively, by amendment to the statute. Citing the pending "FDA Approval Labeling Act" (H.R. 2244), which would allow the statement "FDA APPROVED" followed by the NDA number on prescription drugs, the comment stated that FDA should suggest revisions in this manner to cover the labeling of NDA'd OTC drug products. Another comment contended that section 301(1) can be interpreted to apply only to statements connoting new drug approval pursuant to 21 U.S.C. 355 and therefore any terminology such as "APPROVED USES" connoting use of terminology approved by FDA in a final OTC drug monograph is not prohibited by this section of the law.

The comments maintained that equal treatment of OTC drug products marketed under an NDA and under an OTC drug monograph would be consistent with FDA's policy of promoting uniformity in OTC drug labeling consistent with applicable statutory standards and would lessen consumer confusion about the label indications on OTC drugs because there is no difference to the consumer between an NDA'd and a monograph OTC drug. The comments requested that the agency clarify that the "FDA APPROVED USES" language will also be permitted for NDA'd OTC drugs, and this language will not be in violation of section 301(1) of the act.

To further promote consistency in the labeling of OTC drug products, the agency agrees that OTC drug products approved by an NDA but not included in an OTC drug monograph should also be permitted to use the term "FDA APPROVED USES" or "FDA APPROVED INFORMATION" in their labeling. Because the current regulation is included under Part 330 (21 CFR Part 330), which applies only to OTC drugs that are generally recognized as safe and effective and not misbranded, the agency will propose in a future issue of the **Federal Register** specific procedures for the labeling of OTC drug products subject to NDA's that will allow use of the "FDA APPROVED USES" terminology.

The agency notes further that section 301(1) of the act by its own terms prohibits only representations or suggestions that an approval of an application under section 505 of the act (21 U.S.C. 355) is in effect for a drug product. It does not apply to requirements for labeling related to indications for use such as those described in the present regulation. Accordingly, FDA believes that it can issue regulations for NDA'd OTC drugs that will be consistent with section 301(1) of the act and that a statutory amendment to section 301(1) is not required for this purpose.

8. One comment stated that the second labeling alternative included in the proposal should permit reference to "FDA Approved Uses" because manufacturers or distributors of OTC drug products who use that alternative will be severely penalized by the inability to make reference to the "FDA Approved Uses." Contending that consumers will almost always choose an OTC drug products that has language such as "FDA Approved Uses," the comment added that marketers would be forced to use either alternative 1 or 3 rather than be disadvantaged in the marketplace by using alternative 2. The comment stated that, in practical terms, this means that the previous policy of rigid exclusivity would be perpetuated.

The comment added that denying the right to make reference to "FDA Approved Uses" to the marketer who elected the second alternative would place that marketer at a competitive disadvantage and also would mislead consumers because they would improperly be led to believe that the product bearing the "FDA Approved Uses" language is somehow better than the competing product that does not have such language.

The proposal, and this final rule, provide three alternatives to every manufacturer. A manufacturer who feels competitively disadvantaged by a particular alternative is free to select another alternative, such as one being used by a competitor. Moreover, the agency does not accept the comment's basic premise, that in every instance consumers will prefer a product bearing "FDA Approved" indications. A principal impetus behind the present rulemaking was the belief that there may be many ways of fairly and accurately stating the same information.

A manufacturer may well find that consumers prefer the language it develops over the "FDA Approved" language. The agency believes that substantial numbers of manufacturers will elect to use labeling alternative 3, which combines both the monograph language and the manufacturer's alternative language. This alternative will permit use of the "FDA Approved" designation while also allowing manufacturers flexibility in developing their own wording. In any event, it would be false or misleading to use the words "FDA APPROVED USES" for wording that has not, in fact, been approved by the FDA, as requested by the comment. Accordingly, such a designation may not be used where alternative 2 is selected by a manufacturer.

Manufacturers may also wish to use the FDA monograph language but not use the terminology "APPROVED USES" or "APPROVED INFORMATION." Therefore, the agency has revised the requirements of labeling alternative 1 to make the use of the term "APPROVED USES," or similar designations permitted in the regulation, optional. However, if the term "APPROVED USES" is used, then the indication must appear within a boxed area. Also, the boxed area may not be used unless the "APPROVED USES"designation is also used.

The agency has also revised labeling alternative 2 to delete the reference back to the requirements of paragraph (c)(2)(i), because the original wording was unclear. Alternative 2 has also been clarified to refer only to "other truthful and nonmisleading statements."

9. Several comments stated that manufacturers should be allowed to use more than one of the three alternatives provided in the proposal in the labeling of a particular OTC drug product. As an example, one comment stated that a manufacturer might wish to use the first alternative by listing "APPROVED USES" or "FDA APPROVED USES" in a boxed area on the outer container and also use the third alternative by presenting the same FDA approved indications under "APPROVED USES" or "FDA APPROVED USES" together with alternative truthful and nonmisleading terminology outside the boxed area on the immediate container. Arguing that the third alternative recognizes that a combination of the first and second alternatives is appropriate on a single label, one comment maintained that there is no valid legal or policy reason why a company could not choose the first alternative on the outer container label and the second alternative on the immediate container label. Two comments argued that provided each labeling of an OTC drug product is taken as a whole and is complete, the ability to blend or combine alternatives for use in various component labeling sections would be fully consistent with the intent of the proposal. One comment added that this interpretation maintains the substantive standards of the proposal and preserves the overriding statutory requirement that the labeling not be false or misleading. The comments requested that FDA clarify in the final rule whether more than one alternative may be used.

The agency agrees with the comments that the proposal would enable manufacturers to use more than one of the three alternatives in the labeling of OTC drug products provided that each portion of the labeling complies with applicable statutory and regulatory labeling requirements in all respects. The final regulation has been clarified to state that more than one of the three alternatives may be used in the labeling of any particular OTC drug product marketed under the terms of a final OTC drug monograph.

10. Several comments argued that flexibility of labeling should be applied not only to indications but also to other sections of the labeling, e.g., warnings. One comment claimed that the same arguments could be made for the flexibility of other required labeling, such as directions or warnings, and questioned why, if flexibility of labeling is superior, the proposed rule is limited to indications for use. The comment expressed concern that the proposal "is the crack in the door" and that other required labeling will be given the same treatment later on.

One of the comments discussed the effect of the exclusivity policy, as applied to warnings, directions for use, and statements of identity, on the labeling of multiuse products, such as petrolatum. The comment contended that if a product is simultaneously subject to several final monographs, the policy of exclusivity would require that each specific "warning," "direction for use," and "statement of identity" established in each applicable final monograph be included on the product label, even if they are redundant (though not precisely identical), inconsistent, obvious, or even if their inclusion is impossible because of the small available label space. The comment also contended that the manufacturer would not be permitted to eliminate redundancy and inconsistency, and thereby minimize the burden of compliance, by employing terminology of its own expressing in a truthful and nonmisleading way, the appropriate "warnings," "directions for use," and "statements of identity" based on guidance provided in the applicable final monographs.

The flexibility established by the present regulation does not apply to OTC drug labeling other than indications for use. All other OTC drug labeling must continue to be stated in exact language where exact language has been established and identified by quotation marks in an applicable monograph or by regulation. However, in addition to the indications for use, statements of identity, warnings, and directions may appear within the boxed area. The agency's reasons for this policy are as follows:

Indications for use. As stated in the proposal, the agency recognizes that, within limits, there can be various ways of stating the same thing, some of which may even be more meaningful to potential purchasers of OTC drug products. The agency concludes that it can meet its regulatory responsibilities by providing greater flexibility for the use of alternative truthful statements without recourse to the monograph amendment process, which consumes both time and resources. (See comments 2 and 4 above.)

Statement of identity. Where it is feasible, some flexibility of labeling is already allowed in the statement of identity for certain OTC drug products, e.g., any of the following statements of identity could be used to describe OTC external analgesic drug products: "external analgesic," "topical analgesic," or "pain-relieving (insert dosage form, e.g., cream, lotion, or ointment)." See the tentative final monograph for OTC external analgesic drug products, published in the **Federal Register** of February 8, 1983 (48 FR 5852). For other OTC drug products, only one statement of identity has been proposed, e.g., "nighttime sleep-aid" or "acne medication." The agency concludes that there is no need to extend flexibility of labeling to the statement of identity, because, as stated above, it is already provided for where applicable. The agency believes that uniformity in this area helps avoid consumer confusion and aids consumer selection of competing products. In addition, where a product is marketed with multiple uses, the agency believes that it is essential that each use be identified in the statement of identity, which by regulation (21 CFR 201.61) must appear on the principal display panel of an OTC drug in package form, because the

prominent location of this information greatly helps consumers in selecting an appropriate OTC drug product to use.

Warnings. Unlike indications for use, which pertain to a group of similar OTC drug products, warnings are more likely to be specific to ingredients. The agency believes that concisely and consistently worded warnings are essential to the safe use of an OTC drug product and that permitting flexibility in this section of labeling could put consumers at risk in terms of safe use of an OTC drug product. Accordingly, the exact wording of warnings in an OTC drug monograph will continue to be required. However, where applicable, e.g., in the case of a product covered by several monographs, warnings may be combined to eliminate duplicative words and phrases so long as the resulting warning is clear and understandable. The individual OTC drug monographs already provide for this.

Directions. OTC drug monographs do provide for flexibility in directions relating to the dosage for specific ingredients, which is designated in general terms. It is not FDA's intent that certain parts of the dosing information stated in a monograph be used verbatim. Rather, manufacturers, depending on their specific dosage form and the strength of the dosage form, may vary the dosage directions so long as the directions accurately reflect the designated dosage. For example: for a product which contains 25 milligrams (mg) of an active ingredient in a tablet dosage form where the monograph directions are 25 mg three times a day, the directions could read "Take 1 tablet 3 times a day"; or, the same product could be marketed as a 12.5-mg capsule, in which case the directions could read "Take 2 capsules 3 times a day."

In other instances, usually with topical OTC drug products, the agency believes that the safe and effective use of those products would be better ensured by requiring specific monograph language to be used in labeling directions. In these cases the agency has used quotation marks to identify those portions of the monograph directions that must be used exactly. (See the tentative final monograph for OTC wart remover drug products that was published in the **Federal Register** of September 3, 1982; 47 FR 39102.)

The principles discussed above are applicable to multiuse products, such as petrolatum, which was mentioned in the comment.

11. One comment stated that the "other allowable indications" listed in the more recently published tentative final monographs should also be included in the final monographs and should be allowed to be included in the "FDA Approved Uses" boxed area. The comment contended that only indications that have not been reviewed by the agency should be excluded from the boxed area. Another comment suggested the inclusion in proposed monographs of a section for substitute language.

A number of recently published tentative final monographs have included statements captioned "Other Allowable Indications" or "Other Allowable Statements." These statements are comparable to the substitute language described by one comment. As proposed in those tentative final monographs, other allowable statements describing indications would have been permitted to appear elsewhere on the labeling in addition to the monograph-required information, but could not appear in direct conjuction with the required labeling prescribed by the monograph.

In the exclusivity proposal, the agency stated that these additional indications and statements may be developed during the tentative final monograph stage of the OTC drug review, but would not be included in a final monograph because such statements were only examples of other acceptable language. However, the agency has decided that, because these additional terms have been reviewed by FDA, they should be incorporated, wherever possible, in final OTC drug monographs under the heading "Indications" as part of the indications developed under that monograph. By inclusion in the final monograph, they would therefore be permitted to be included in the boxed area. As future final monographs are published, the indications for use section will include such terms, where appropriate. This approach will provide other substitute language as suggested by one comment. As one comment stated, only indications that have not been reviewed by the agency [as well as those found to be nonmonograph in OTC drug rulemaking would then be excluded from the boxed area.

12. Several comments expressed concern about the agency's review of OTC drug labeling and the enforcement of violations under the revised exclusivity policy. One of the comments recommended that a manufacturer be required to send a registered letter to FDA outlining its intentions prior to ordering the printing of any labeling which changes the labeling contained in an approved monograph. The comment stated that this would not be a request for approval—just apprising FDA of what is being undertaken. Stating that the registering of the letter would be for the manufacturer's protection, the comment added that it would then be up to FDA to expedite an analysis of the change. The comment concluded that in this way FDA could stay abreast of all situations and still give the manufacturer more latitude to develop the product.

Several comments argued that without prior FDA approval the use of alternative indication statements would increase the cost of enforcing violations and strain FDA resources by "adding another layer of waiting, negotiation, and review to validate or prohibit statements which may not be truthful and not misleading." Two comments contended that the agency will find it impossible to review and police the infinite variations in language developed as marketers compete to sell their products.

One comment maintained that enforcement will be more cumbersome and difficult for FDA under a revised policy than under the existing exclusivity policy, but will be easier than if the agency had completely abandoned the approved terminology in the OTC drug monographs. The comment added that the monograph terminology will provide a workable standard by which to measure whether alternative terminology accurately expresses the approved indications for use or misbrands the product. Another comment supporting the more flexible labeling approach added that safeguards on checking the labeling language will need to be implemented, while another comment stated that FDA does not enforce regulations as it should now, thus allowing manufacturers enough freedom as it is.

One comment noted that alternative language used in labeling will still be subject to the controlling safeguard that it must be truthful and not misleading and that its substance not render the product misbranded or a new drug requiring FDA approval. The comment added that these continuing standards and FDA monitoring will provide adequate assurance to the public that health and safety considerations are fully taken into account and not overlooked.

Several comments, although less directly related to the question of FDA's review and enforcement of labeling requirements, are appropriate for inclusion here. Contending that the public does not know the subtleties involved in the wording in each product label, one of these comments stated that it will take a great deal of publicity to inform most people, particularly the most vulnerable, that the policy has

become caveat emptor (let the buyer beware). Another comment contended that the proposed rule represents abandonment of FDA's commitment to consumer protection for OTC drug products and would "turn back the clock and re-establish the rule of Caveat Emptor wherever these products are sold."

The agency does not believe it is necessary to require manufacturers to notify FDA by registered mail of any intended changes from monograph labeling. A manufacturer may choose other truthful and nonmisleading language to describe the indications for use, subject to the statutory prohibition against misbranding by the use of false or misleading labeling. As comments noted, the agency emphasizes that the monograph language will be used as a regulatory benchmark to ensure that any alternative language does not exceed the approved indications.

In reference to the comments' concern regarding the difficulty and costliness of enforcement, the agency has routine compliance activities to evaluate OTC drug labeling and will in the normal course of business made determinations as to whether a manufacturer has exceeded the labeling allowed by a final monograph. FDA will carefully examine any alternative language that manufacturers use to ensure that it does not go beyond the approved indications. Accordingly, consumers will continue to be protected. In addition, the agency concludes that the revised rule does not reestablish "caveat emptor." As stated above, FDA will continue to review OTC drug labeling and institute appropriate enforcement action when violations are determined to exist.

13. One comment stated that the use of the term "FDA Approved" on OTC drug labeling prior to promulgation of a final OTC drug monograph is not a true statement, and would, therefore, constitute misbranding. Another comment stated that consumer confusion will result in certain categories of OTC drug products that are subject to a final monograph, such as antacids, could use the "FDA Approved" language while other categories of products could not bear the language because final monographs for those products have not yet been issued. The comment contended that it would appear to consumers as though drugs without the "FDA Approved" designation are "unapproved."

The first comment is correct; until relevant individual OTC drug monographs are issued in final form, the boxed area/"APPROVED USES" concept described in this final rule can not be implemented. A product can not bear an "APPROVED USES" designation until the use has, in fact, been approved by FDA, which will only occur when the final monograph is issued.

In response to the second comment, FDA does not believe that consumers will be confused while the use of "FDA Approved" language is being implemented as final monographs are issued. As the "FDA Approved" language is implemented on a class-by-class basis as final monographs for each class of OTC drug products are issued, all drugs within that class will be implementing the monograph and "FDA Approved" language at the same time. Therefore, competitive products within a particular class of OTC drugs will have similar labeling at or about the same time.

14. Two comments requested that the final rule on exclusivity clearly state that the revised labeling requirements do not apply to cosmetic or cosmetic/drug products. One of the comments maintained that the first alternative treats cosmetic/drug and cosmetic products unfairly because cosmetic/drug products may be precluded from using truthful and nonmisleading cosmetic terminology on key parts of a product label if the first or third alternative is used. The comment added that cosmetic terminology is not reviewed and approved by FDA in the OTC drug monographs and therefore could not be placed in the box. Stating that there are many examples in the marketplace of truthful, nonmisleading cosmetic terminology on the label with drug terminology, the comment added that it is not aware of any consumer confusion from this common practice nor of any expressed agency concern that such a practice would adversely affect the public health. Another comment stated that the options included in the proposal are particularly valuable to products that make both drug and cosmetic claims, because consumers could find a complete description of the product's claims at one location on the label, thus minimizing confusion about the product's performance.

OTC drug monographs cover only the drug use of the active ingredients listed therein and do not apply to the use of the same ingredients in products intended solely as cosmetics. Thus, the final rule does not apply to products marketed solely as cosmetics. However, products labeled for both drug and cosmetic use must conform to the requirements of the pertinent final OTC drug monograph(s), the cosmetic labeling requirements of section 602 of the act (21 U.S.C. 362), and 21 CFR Part 701. As one comment pointed out, cosmetic terminology is not reviewed and approved by FDA in the OTC drug monographs and therefore could not be placed in the box. Thus, cosmetic claims may appear elsewhere in the labeling but not in the box should manufacturers choose alternative one or three for labeling cosmetic/drug products.

15. Several comments included suggestions on various aspects of OTC drug labeling. These included use of simple language, larger print size, pictorial illustrations to make labeling more readily understandable to consumers with impaired vision or limited reading skills, print and/or color contrasts to highlight cautions in using the drug(s), and having terms used in a monograph reflect a greater range of detailed language. One comment suggested that indications worded by a manufacturer should also be boxed, i.e., "NOT APPROVED BY FDA" and color-coded red to distinguish them from "FDA APPROVED" language, which would be color-coded green, while another comment asserted that there would be less confusion if an elipse was used for alternative language and entitled "INFORMATION ACCEPTED BY FDA."

The agency appreciates the comments' suggestions about OTC drug labeling. However, most of these items are already covered by other existing regulations, e.g., 21 CFR 201.15 (prominence of required label statements) and 21 CFR 201.60 (principal display panel), and are outside the scope of this rulemaking.

The agency disagrees with the comments' suggestions that indications worded by a manufacturer should be contained in an elipse or be boxed and color-coded to distinguish those indications from "FDA Approved" language. The agency believes that these suggestions would be confusing and would add little to consumer understanding of OTC drug labeling. In addition, because alternative language is not preaccepted by FDA, the agency concludes that it will be less confusing to consumers if only a single boxed area is used in OT drug labeling wherein only exact monograph language need appear.

16. Several comments expressed concern about the inclusion of side effects and warnings in OTC drug labeling. One comment stated that the manufacturer's goal is to make money; consequently, side effects, as well as interaction with foods, are likely to be glossed over. Another comment stated that drugs are potential poisons and that a number of unwanted reactions occur already, while another comment cited

upset stomach or bleeding that may be caused by aspirin as an example. Another comment noted that warning against use by persons with certain conditions, e.g., diabetes, heart conditions, and thyroid problems, are not foremost on the label or container, but are often in small print near the end of the label or are located on the inside of a container. The comment contended that these warnings should be in large print, at the top of the label, and in a boxed area.

Another comment emphasized that all OTC drug labeling should be required to state the age range for usage, e.g., "Administer only to persons aged 12–70. For persons outside this age range, consult your physician before administering it."

The agency shares the comments' concerns over the necessity of OTC drug labeling to alert consumers to the potential side effects of the product, conditions under which the product should be used with caution, and proper directions for use including age ranges. These items are being addressed in individual OTC drug rulemakings, specific to ingredients contained in OTC drug products. Regarding one comment's suggestion that other labeling, e.g., warnings and dosing information, may be included within the boxed area, the agency notes that the proposal and final regulation provide that option.

17. Referring to the proposed conforming amendment for OTC antacid drug products (21 CFR 331.30), published simultaneously with the exclusivity proposal at 50 FR 15814, two comments noted that it is made clear that, of the several indications listed, it is optional to select any one, some, or all of the indications for use on the product label and labeling. The comments requested that this policy expressly be set forth in the exclusivity proposal itself to clarify that such a policy is applicable to all OTC drug monographs, rather than stating it on a monograph-by-monograph basis.

The agency agrees that labeling should be as flexible as possible as evidenced by the final monograph for OTC antacid drug products. Because the various OTC drug monographs differ in the manner in which "Indications" are described (e.g., a single indication, a broad indication with optional terms, or several indications), the agency considers it more appropriate to apply this selection policy on a monograph-by-monograph basis where applicable. The agency does not believe it necessary to establish an additional regulation to clarify this policy because manufacturers will need to read individual monographs applicable to their products to determine what options are available.

II. Summary of Changes

1. The agency has clarified the final regulation to state that more than one of the three alternatives may be used in the labeling of an OTC drug product. (See comment 9.)

2. The final rule has been clarified to state that labeling information not identified by quotation marks in a monograph, such as dosage, need not appear in OTC drug product labeling in the exact language established in an OTC final monograph. (See comment 10.)

3. The agency has revised alternative 1 to make the use of the term "FDA APPROVED USES," or similar designations permitted in the regulation, optional. However, as described in the proposal, if the term "FDA APPROVED USES" is used, then the indications information must appear within a boxed area. The boxed area may not be used unless the "FDA APPROVED USES" terminology is also used. The agency has also clarified the wording of alternative 2. (See comment 8.)

4. The agency has clarified the regulatory provisions of alternatives 2 and 3 to read "the provisions of section 502 of the act relating to misbranding" and the "prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act." These changes have also been incorporated into the conforming amendments that were proposed for the monographs for OTC antacid, antiflatulent, and cholecystokinetic drug products in 21 CFR Parts 331, 332, and 357, respectively

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (50 FR 15813). The agency has examined the economic consequences of this final rule 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 not one of these rules, including this final rule for labeling of drug products for OTC human 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, Public Law 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 labeling of drug products for OTC human use is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects

21 CFR Part 330

OTC drugs, Labeling requirements.

21 CFR Part 331

OTC drugs, Antacid drug products.

21 CFR Part 332

OTC drugs, Antiflatulent drug products.

21 CFR Part 357

OTC drugs, Cholecystokinetic drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 330, 331, 332, and 357 as follows:

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

1. The authority citation for 21 CFR Part 330 is revised as set forth below and the authority citations under §§ 330.2, 330.10, and 330.12 are removed.

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

§ 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. At the option of the manufacturer, this labeling may be designated "APPROVED USES," or be given a similar designation as permitted by this paragraph, each time it appears in the labeling, e.g., on the outer carton, inner bottle label, and on any package insert or display material. If the "APPROVED USES" or a similar designation is used, the labeling involved shall appear within a boxed area. 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 and identified by quotation marks in an applicable monograph or by regulation (e.g., § 201.63 of this chapter). 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, or "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 may contain in a prominent and conspicuous location other truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act. Such labeling shall not be boxed and shall not contain the statements provided in paragraph (c)(2)(i) of this section relating to "APPROVED USES," or "APPROVED INFORMATION," or contain a statement 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 boxed-area 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 provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(iv) At the option of the manufacturer, more than one of the alternatives described in paragraphs (c)(2)(i), (ii), and (iii) may be used in separate labeling, e.g., container label, outer carton, package insert, display material, for a particular OTC drug product provided each labeling complies with all applicable statutory and regulatory labeling requirements in all respects.

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

(vi) Regardless of the alternative 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 where exact language has been established and identified by quotation marks in an applicable monograph or by regulation (e.g., § 201.63 of this chapter).

* * * * *

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

3. The authority citation for 21 CFR Part 331 is revised 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

4. In Part 331, § 331.30 is amended 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 provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

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

5. The authority citation for 21 CFR Part 332 is revised 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.

6. In Part 332, § 332.30 is amended 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 provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

* * * * *

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

7. The authority citation for 21 CFR Part 357 is revised 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.

8. In Part 357, § 357.250 is amended 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 provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

April 14, 1986.

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