DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 92N–454A]

RIN 0910–AA01

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its general labeling policy for over-the-counter (OTC) drug products to allow for the interchangeable use of certain labeling terms required by an OTC drug monograph. Examples of words already allowed include: ''doctor'' or ''physician,'' ''consult'' or ''ask,'' and ''indications'' or ''uses.'' This proposal provides an additional phrase (''unless a doctor tells you'') that can be used in place of several other phrases found in various OTC drug monographs.

DATES: Written comments by May 20, 1996; written comments on the agency's economic impact determination by May 20, 1996. The agency is proposing that any final rule that may issue based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2304.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of April 5, 1993 (58 FR 17553), the agency proposed to amend its general labeling policy for OTC drug products to allow for the interchangeable use of certain words in the labeling required by an OTC drug monograph. The agency had previously proposed in a number of tentative final monographs and included in a number of final monographs a provision that the words ''doctor'' and ''physician'' may be used interchangeably in the labeling of OTC drug products. Instead of including this provision in each OTC drug monograph, the agency proposed to include such a provision in § 330.1 (21 CFR 330.1) as part of the general conditions under which an OTC drug is generally recognized as safe, effective, and not misbranded. The agency also proposed that, at manufacturers' discretion, the word ''ask'' could be substituted for the word ''consult,'' which appears in the directions for many OTC drug monograph ingredients. Thus, the agency proposed that the phrases ''consult a physician,'' ''consult a doctor,'' ''ask a physician,'' and ''ask a doctor'' could be used interchangeably. The agency invited comments and suggestions as to such other terms that could be used interchangeably, i.e., terms general in nature that appear in more than one OTC drug monograph. The comments received in response to the proposed rulemaking were favorable and suggested a number of additional terms that could be used interchangeably.

In a final rule published in the Federal Register of January 28, 1994 (59 FR 3998), the agency allowed the following terms to be used interchangeably in the labeling of OTC drug products: (1) ''Ask'' or ''consult,'' (2) ''assistance'' or ''help,'' (3) ''clean'' or ''cleanse,'' (4) ''continue'' or ''persist,'' (5) ''continues'' or ''persists,'' (6) ''doctor'' or ''physician,'' (7) ''indication'' or ''use,'' (8) ''indications'' or ''uses,'' and (9) ''lung'' or ''pulmonary.'' These terms are included in § 330.1(i).

In the Federal Register of August 3, 1994 (59 FR 39499), the agency proposed to amend § 330.1(i) so that the phrases ''Drug interaction precaution,'' ''Avoid mixing drugs,'' or ''Do not mix drugs'' could be used interchangeably. The agency also requested public comment on changing the wording of warnings from negative phraseology to a more positive approach (e.g., ''Do not use more than 7 days'' to ''Use only 7 days,'' ''Do not use in * * *'' to ''Avoid use in * * *,'' ''Do not use longer than 1 week * * *'' to ''Use only 1 week * * *,'' and ''Do not use this product except under the advice and supervision of a physician if * * *,'' to ''Use only with a physician's help if * * *'' or ''Use only with the help of a doctor if * * *'').

The agency has received a number of comments on the proposal, and they are being evaluated at this time. The agency intends to publish a final rule in a future issue of the Federal Register.

The agency intends to continue to examine labeling required by OTC drug monographs to provide consumers more simplified and understandable information. This includes interchangeable terms, alternative phraseology, and possibly a new or different labeling format. At this time, the agency is proposing an additional phrase that could be used interchangeably.

Labeling information about not using an OTC drug product under certain circumstances (e.g., ''unless directed by a doctor,'' or ''except under the advice and supervision of a physician'') appears in different OTC drug monographs in different language. This has occurred because various OTC advisory review panels recommended different wording, and OTC drug rulemakings have been completed over a period of years.

The phrase ''* * * unless directed by a doctor'' appears in the warning statements of many recent OTC drug monographs. (See, for example, § 341.76(c)(2) (21 CFR 341.76(c)(2)) which states: ''Do not use this product if you have * * * unless directed by a doctor.'') In a number of other monographs, terms with the same (or similar) meaning have been used. For example, the OTC antacid drug products monograph in § 331.30(c)(1) and (c)(4) through (c)(7) (21 CFR 331.30(c)(1) and (c)(4) through (c)(7)) uses the phrase ''except under the advice and supervision of a physician,'' and the OTC ophthalmic drug products monograph in § 349.75(c)(2) (21 CFR 349.75(c)(2)) uses the phrase ''except under the advice and supervision of a doctor.'' That terminology has not been used in more recent OTC drug monographs.

For OTC antihistamine drug products in § 341.72(c)(3) and (c)(4) (21 CFR 341.72(c)(3) and (c)(4)), and for OTC anorectal drug products in § 346.50(c)(7)(ii) (21 CFR 346.50(c)(7)(ii)), the phrase ''* * * without first consulting your doctor'' is used. In § 341.72(c)(6)(i) through (c)(6)(iii), the phrase ''* * * without first consulting the child's doctor'' is used. The warning statements for OTC dandruff, seborrheic dermatitis, and psoriasis drug products in § 358.750(c)(2)(ii), (c)(3), and (c)(4) (21 CFR 358.750(c)(2)(ii), (c)(3), and (c)(4)) include the phrases ''* * * without consulting a doctor,'' ''* * * except on the advice of a doctor,'' and ''* * * unless directed to do so by a doctor.'' Thus, a number of different phrases have been used to convey the same message. The phrase ''unless directed by a doctor'' has been used more recently and most frequently.

The agency believes that all of these phrases can be interpreted in the same way (e.g., ''* * * unless a doctor tells you''). The agency believes this simpler phrase may be better understood by consumers than some of the other phrases. Accordingly, the agency is proposing to amend § 330.1(i) to include the phrase ''unless a doctor tells you'' as an alternative for these other phrases

where they appear in the labeling of OTC drug products. In a few instances, the words ''or your child's doctor'' would be used as part of this phrase. The agency is asking whether it would be preferable to say ''your'' child's doctor or ''the'' child's doctor, or whether it does not make any difference which wording is used. The agency is requesting comment from manufacturers, health professionals, and consumers on whether it would be desirable to use this alternative phrase interchangeably with the other phrases and/or whether a single uniform phrase should appear in all of the cited regulations. The agency also seeks comment whether there are additional, simpler, informative ways in which this information may be stated.

II. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and, thus, is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. If this proposed rule becomes a final rule, the labeling options could be implemented at very little cost by manufacturers at the next printing of labels, for those products for which the manufacturer chooses to make a change. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on the labeling of OTC drug products. Types of impact may include, but are not limited to, costs associated with relabeling. Comments regarding the impact of this rulemaking on OTC drug products should be accompanied by appropriate 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.

III. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed labeling statements are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

IV. Environmental Impact

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

Interested persons may, on or before May 20, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Written comments on the agency's economic impact determination may be submitted on or before May 20, 1996. Three copies of all comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 330

Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 330 be amended 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 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 330.1 is amended by adding new paragraph (i)(11), to read as follows:

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

* * * * *

(i) * * *

(11) ''Unless a doctor'' (or ''your child's doctor,'' where applicable) ''tells you'' may be used in place of any of the following phrases:

(i) ''Except on the advice of a doctor''.

(ii) ''Except under the advice and supervision of a'' [''physician'' or ''doctor''].

(iii) ''Unless directed by a doctor''.

(iv) ''Unless directed to do so by a doctor''.

(v) ''Without consulting a doctor''.

(vi) ''Without first consulting your'' (or ''your child's'' or ''the child's'') ''doctor''.

* * * * *

Dated: February 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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