DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 92N–0454]

RIN 0905–AA06

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 modifying a proposed rule that proposed to amend the general labeling policy for over-the-counter (OTC) drug products to allow for interchangeable use of the terms ''Drug interaction precaution,'' ''Avoid mixing drugs,'' or ''Do not mix drugs'' in labeling required by an OTC drug monograph. This modification provides for one additional alternative term, ''Do not use with * * *.''

DATES: Written comments by January 2, 1996; written comments on the agency's economic impact determination by January 2, 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–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 3, 1994 (59 FR 39499), the agency proposed to amend its general labeling policy for OTC drug products to allow for the interchangeable use of the terms ''Drug interaction precaution'' or ''Avoid mixing drugs'' or ''Do not mix drugs.'' The agency stated its belief that the phrase ''Avoid mixing drugs'' or ''Do not mix drugs'' may be better understood by consumers than ''Drug interaction precaution.'' The agency specifically invited comments on whether the terms ''Avoid mixing drugs'' or ''Do not mix drugs'' could be used interchangeably with the term ''Drug interaction precaution.'' Further, the agency requested comments on whether it would be desirable to change negatively worded warnings to more positive phraseology (e.g., ''Do not use more than 7 days'' to ''Use only 7 days''). The agency also asked for comment concerning the desirability of identical warning language for similar OTC drug products.

The agency received a number of comments in response to the proposed rule. Those comments are being evaluated. The agency is modifying the proposal to include another alternative term and reopening the administrative record to allow for comments on this alternative term.

II. The Additional Term

The agency believes that there may be a simpler way to alert consumers to this type of information. The agency is proposing an additional term, ''Do not use with * * *,'' as an alternative to the proposed interchangeable terms. For example, the current drug interaction precaution in § 341.76(c)(4) (21 CFR 341.76(c)(4)) begins with the words ''Do not use this product * * * '' following the words ''*Drug interaction precaution*.'' If this new approach were used, the words ''Drug interaction precaution'' would no longer be needed and the precaution would begin with ''*Do not use with*'' and could be followed by ''a prescription drug for * * *.'' This approach would shorten the required labeling without changing the meaning. The agency would like comment on this approach and whether this term would be desirable for all OTC drug product labeling.

III. Analysis of Impacts

The economic impact and the environmental impact statements remain the same as stated in the proposed rule (59 FR 39499 at 39500).

Interested persons may, on or before January 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this amended proposal. Written comments on the agency's economic impact determination may be submitted on or before January 2, 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 redesignating paragraphs (i)(7), (i)(8), and (i)(9) as paragraphs (i)(8), (i)(9), and (i)(10), respectively, and by adding new paragraph (i)(7) to read as follows:

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

* * * * *

(i) * * *

(7) ''Drug interaction precaution'' or ''Avoid mixing drugs'' or ''Do not mix drugs'' or ''Do not use with * * *''.

* * * * *

Dated: September 25, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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