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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. 99D-5013]

Draft Guidance for Industry on **Labeling** of Over-the-Counter Human Drug Products Using a Column Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ``**Labeling** of Over-the-Counter Human Drug Products Using a Column Format.'' This draft guidance is intended to provide information on the use of columns as part of the standardized format and standardized content requirements for the **labeling** of over-the-counter (OTC) drug and drug-cosmetic products.

DATES: Submit written comments on the draft guidance for industry by January 31, 2000.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance entitled ``**Labeling** of Over-the-Counter Human Drug Products Using a Column Format'' to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow or Cazemiro R. Martin, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ``**Labeling** of Over-the-Counter Human Drug Products Using Column Format.'' This is the first of a series of guidances the agency plans to issue to help manufacturers, packers, and distributors implement the recently issued final rule establishing standardized format and content requirements for the **labeling** of all OTC drug products.

In the Federal Register of March 17, 1999 (64 FR 13254), FDA published a final rule establishing a standardized format and standardized content requirements for the **labeling** of all OTC drug

products including drug-cosmetic products (products that consist of both drug and cosmetic components or a single component marketed for both drug and cosmetic uses). This rule is intended to standardize **labeling** for all OTC drug products so consumers can easily read and understand OTC drug product **labeling** and use these products safely and effectively.

The regulatory requirements for this new standardized **labeling** require manufacturers to present OTC drug and drug-cosmetic **labeling** information in a certain prescribed order and format. This new format will require the revision of all existing **labeling.**

The final rule did not include examples where Drug Facts information (presented in a defined box or similar enclosure) appeared in column format on the same side of the outside container of a retail package, or side-by-side on the immediate container label. This draft guidance is intended to explain how Drug Facts information can be presented using a column format that is consistent with the final rule. This draft guidance includes examples of such **labeling** in columns.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This draft guidance represents the agency's current thinking on using a column format in the **labeling** of OTC human drug products (21 CFR part 201). It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may, on or before January 31, 2000, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 22, 1999.
Margaret M. Dotzel,
Acting Associate Commissioner for Policy.
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