published March 14, 1991 (56 FR 10906), the agency announced that it would deny, without prejudice, any health claim petition that was submitted before issuance of final regulations concerning the submission and content of such petitions.

Dated: November 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31122 Filed 11–30–99; 8:45 am]

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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Draft Guidance for Industry on Labeling of Over-the-Counter Human Drug Products Using a Column Format; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling of Over-the-Counter Human Drug Products Using a Column Format.'' This draft guidance is intended to provide information on the use of columns as part of the standardized format and standardized content requirements for the labeling of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DATES: Submit written comments on the draft guidance for industry by January 31, 2000.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance entitled ''Labeling of Over-the-Counter Human Drug Products Using a Column Format'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling of Over-the-Counter Human Drug Products Using Column Format.''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.

[FR Doc. 99–31124 Filed 11–30–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–285]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection.

Title of Information Collection: Request for Retirement Benefit Information.

Form No.: HCFA–R–285 (OMB# 0938–0769).

Use: This form will be used to obtain information regarding whether a beneficiary is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan subsidizes the beneficiary's Part A premium. The purpose in collecting this information is to determine and provide those eligible beneficiaries, with free Part A Medicare coverage.

Frequency: On occasion.