for the year prior to the intervention. The effect of the second intervention will be evaluated experimentally (using a control group), measuring the screening behaviors from the time of the reminder letter to the Time-2 interview 6 months later, compared to the screening behaviors at the Time-1 interview.

These intervention evaluations will address barriers to cervical screening and also will allow insight into the following questions:

1. Does the outreach message have a long-term impact concerning the use of cancer screening services (message retention and actual screening behavior)?

2. Does receiving a screening reminder affect message retention and actual screening behavior?

The total cost to all respondents (current dry cleaners and surviving dry cleaners from the NIOSH mortality study) in the two-year study is estimated at $2733.46 based on an average wage of $10.79 per hour.

Respondents	No. of respondents	No. of responses	Avg. burden Per response (in hrs.)	Total burden (in hrs.)
Year 1	400	1	20/60	133.3
Year 2	360	1	20/60	120.0
Total	.....	.....	.....	253.3

Dated: December 8, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention, (CDC).

[FR Doc. 00–32204 Filed 12–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1584]

Draft Guidance for Industry on Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals.'' The draft guidance is intended to provide information on procedures for requesting an exemption or deferral in accordance with the final rule that established standardized format and content requirements for the labeling of over-the-counter (OTC) human drug products.

DATES: Submit written comments on the draft guidance by February 20, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 requests. 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, 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 OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals.'' This is one of a series of guidances intended to help manufacturers, packers, and distributors implement the final rule establishing standardized format and content requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized format and content requirements for the labeling of all OTC drug products, including drug-cosmetic products. This rule is intended to standardize labeling for all OTC human drug products to help consumers read and understand the product labeling and use these products safely and effectively.

This draft document is intended to provide guidance on the format and procedures for submitting requests for exemptions and deferrals from the requirements of the rule.

This draft guidance is being issued consistent with FDA's good guidance regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on exemptions and deferral procedures related to 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 submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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: December 4, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32195 Filed 12–18–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–5013]

Guidance for Industry on Labeling 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 guidance for industry entitled ''Labeling OTC Human Drug Products Using a Column Format.'' This guidance is intended to provide information on the use of columns as part of the standardized content and format requirements for the labeling of over-the-counter (OTC) drug and drug-cosmetic products.

DATES: The guidance for industry is effective December 19, 2000. Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance 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 requests. Submit written comments on the 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 guidance for industry entitled ''Labeling OTC Human Drug Products Using a Column Format.'' This is one of several guidances the agency is developing to help manufacturers, packers, and distributors implement the recently issued final rule establishing standardized content and format requirements for the labeling of all OTC drug products. Once finalized, these guidances will supersede all other statements, feedback, and correspondence provided by the agency on these matters since the issuance of the final rule.

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA published a final rule establishing standardized content and format 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 regulation for this new standardized labeling requires manufacturers to present OTC drug and drug-cosmetic labeling information in a prescribed order and format.

The agency received a number of inquiries about the use of columns in OTC drug product labeling under the new regulation. To address those inquiries, in the **Federal Register** of December 1, 1999 (64 FR 67291), FDA published a notice announcing the availability of a draft guidance entitled ''Labeling Over-the-Counter Human Drug Products Using a Column Format,'' which would make recommendations about how to use columns in OTC drug product labeling in a way that is consistent with the regulation. The notice invited interested persons to submit comments on the draft guidance by January 31, 2000. In response, the agency received four comments from national trade associations representing manufacturers and distributors of OTC drug and drug-cosmetic products and from manufacturers of OTC drug products.

In addition to allowing two or more Drug Facts boxes on the same side of a package (as stated in the draft guidance), the comments requested that FDA: (1) Allow the use of columns within a single Drug Facts box or, at a minimum, within headings (e.g., the ''Warnings'' section of the labeling); (2) eliminate the ''Drug Facts (continued)'' requirement from the top of the second (and additional, if present) Drug Facts boxes on the same side of a package and eliminate the use of an arrow leading to the next panel; (3) if columns are allowed within a single Drug Facts box, eliminate the requirement that subsequent columns begin with a heading or subheading; (4) replace ''Drug Facts (continued)'' at the top of a second (or subsequent) column with the previous heading or subheading that appears in the labeling and add ''(continued)'' when information continues from one column to another; (5) eliminate the recommendation in the draft guidance that multiple columns should be approximately the same size; and (6) provide an alternate way to present active ingredient and purpose information on narrow panels e.g., active ingredient information on one line and the purpose directly below it).

As a general matter, the requests go beyond what the final rule provides for in labeling OTC drug products. In particular, the proposed use of ''columns within columns'' would represent a significant departure from the overall look and format of the final rule. The agency also believes it is important to maintain the current requirements regarding the use of ''signals'' to show the continuation of the required labeling from one column or panel to the next. The use of such signals is important for the continuous flow of information on the ''Drug Facts'' label. These signals provide a valuable visual cue for introducing the next column of information, without unnecessarily distracting or confusing the reader.

The agency also will continue to recommend that multiple columns on the same side of a package be uniform in size to make it easier for consumers to follow and read the labeling information. The agency believes that the use of different size columns could be distracting and cause consumers to miss important labeling information. Finally, although the final rule requires that the active ingredient and purpose be stated on the same line, this final guidance clarifies that the final rule permits the dosage unit information to be stated directly underneath the active ingredient.

This guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The 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. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. 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 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: December 4, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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