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]

BILLING CODE 4163–18–P

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Draft Guidance for Industry on Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling OTC Human Drug Products—Submitting Requests for Exemptions and Deferrals.'' The draft guidance is intended to provide information on procedures for requesting an exemption or deferral in accordance with the final rule that established standardized format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DATES: Submit written comments on the draft guidance by February 20, 2001.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ADDRESSES: Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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]

BILLING CODE 4160–01–F

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.