

gather evidence on whether a labeling statement on a specific product marketed in a specific context could produce the alleged harm and the harm is material.

In addition to protecting consumer health from harms caused by deceptive product labeling, however, the agency's mission also calls for advancing consumer health by providing information about food products to help consumers improve their health and decrease the risk of contracting diseases by making sound dietary choices. The study was proposed with this mission in mind and, therefore, neither intends, nor is designed to demonstrate any harm attributable to any specific health messages on any specific products. As

stated in the 60-day notice, the study will hold back-panel information (e.g., nutrient contents) constant between front-panel conditions for a given food product. Furthermore, the nutrient contents of test products will meet current regulatory standards for various health messages. Therefore, by design, the study approach precludes any attempt to examine any potential harm as purported in the comment. Instead, the study approach is commonly used and accepted by researchers for the purpose of investigating communication efficacy of label stimuli.

Health messages such as health claims are intended for use by all qualifying marketers and in all qualifying products, rather than certain specific

marketers or products. Hence, under the agency's regulatory regime, the study does not intend to examine specific claims on specific products in specific contexts, as individual marketers would do. Rather, the study will attempt to illustrate possible consumer responses to different types of health messages that may be found on packages of various food products. Finally, the agency notes that, despite the discordance between experimental contexts and the real world, experimental findings are widely recognized and accepted as the best available evidence to demonstrate communication efficacy.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	60	1	60	0.5	30
Invitation	2,000	1	2,000	0.02	40
Interview, Phase 1	1,060	1	1,060	0.17	180
Interview, Phase 2	1,060	1	1,060	0.25	265
Total					515

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Prior to the administration of the interview, the agency plans to conduct pretests of the final questionnaires to minimize potential problems in administration of the interviews. The pretests, each lasting 30 minutes (0.5 hours), will be conducted in up to 3 waves, each with 20 participants. A contractor will send 2,000 e-mail invitations to recruit participants. We assume 50 percent of those contacted will agree to participate in the interviews (1,060 respondents). The interviews are expected to last 10 minutes (0.17 hours) and 15 minutes (0.25 hours) for phase 1 and phase 2, respectively.

The planned sample size per condition is approximately 120. The agency expects small main effects. Therefore, the planned sample size should yield a power of 0.8 at the 0.05 significance level.

Dated: April 13, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2004N-0470]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; New Animal Drugs For Investigational Use**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Fax written comments on the collection of information by May 20, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on

the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B-41, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**New Animal Drugs for Investigational Use—21 CFR Part 511 (OMB Control Number 0910-0117)—Extension**

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for approval of new animal drugs. Section 512(j) of the act (21 U.S.C. 360b(j)), authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). A sponsor

must submit to FDA a Notice of Claimed Investigational Exemption (INAD), before shipping the new animal drug for clinical tests in animals. The INAD must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any nonclinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible

tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that distribution is controlled to prevent potential abuse. The agency utilizes these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms,

academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical profession. Respondents to this collection of information are the persons who use new animal drugs investigational.

In the **Federal Register** of November 10, 2004 (69 FR 65198), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
511.1(b)(4)	190	4.09	778	8	6,224
511.1(b)(5)	190	0.58	110	140	15,400
511.1(b)(6)	190	.01	20	1	20
511.1(b)(8)(ii)	190	.005	1	20	20
511.1(b)(9)	190	.10	20	8	160
Total					21,824

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
511.1(a)(3)	190	2.11	400	9	3,600
511.1(b)(3)	190	4.20	798	1	798
511.1(b)(7)(ii)	400	3.00	1,200	3.5	4,200
511.1(b)(8)(i)	190	6.38	1,200	3.5	4,200
Total					12,798

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the time required for reporting requirements, record preparation and maintenance for this collection of information is based on agency communication with industry. Additional information needed to make a final calculation of the total burden hours (i.e. the number of respondents, the number of recordkeepers, the number of INAD applications received, etc.) is derived from agency records.

Dated: April 13, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0469]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 20, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written