TABLE 1.—ESTIMATED ONE-TIME REPORTING BURDEN [1]

| | No. of Respondents | Annual Frequency per Response | Total annual Responses | Hours Per Response | Total Hours |
|---|---|---|---|---|---|
| Domestic address or telephone number labeling requirement (21 U.S.C. 343(y)) | 1,460 | 38.0822 | 55,600 | 4 | 222,400 |
| FDA recommendation for label statement explaining purpose of domestic address or telephone number | 1,460 | 38.0822 | 55,600 | 4 | 222,400 |
| Total | | | | | 444,800 |

[1] There are no capital costs or maintenance and operating costs associated with this collection of information.

Dated: February 17, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–3916 Filed 2–23–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2007–D–0429] (formerly Docket No. 2007D–0496)**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers

**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). Elsewhere in this issue of the **Federal Register**, FDA is announcing that a proposed collection of information regarding dietary supplement labeling requirements and recommendations has been submitted for OMB review.

**DATES:** Fax written comments on the collection of information by March 26, 2009.

**ADDRESSES:** 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the title ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

**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.

### Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109–462, 120 Stat. 3469). This law amends the Federal Food, Drug, and Cosmetic Act (the act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application.

Section 502(x) of the act (21 U.S.C. 352(x)), which was added by Public Law 109–462, requires the label of a nonprescription drug product marketed without an approved application in the United States to include a domestic address or domestic telephone number through which a responsible person may receive a report of a serious adverse event associated with the product. In the **Federal Register** of January 2, 2008 (73 FR 196), FDA announced the availability of a draft guidance document entitled ''Questions and Answers Regarding the Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' In the **Federal Register** of December 11, 2008 (73 FR 75436), FDA published a notice of availability of a revised version of the same draft guidance document. The guidance document contains questions and answers relating to the labeling requirement and provides guidance to industry on the following topics: (1) The meaning of ''domestic address'' for purposes of the labeling requirements of section 502(x) of the act; (2) FDA's recommendation for the use of an introductory statement before the domestic address or telephone number that is required to appear on the product label under section 502(x) of the act; and (3) FDA's intent regarding enforcing the labeling requirements of section 502(x) of the act.

*Title*: Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.

*Description of Respondents*: Respondents to this collection of information are manufacturers, packers, and distributors whose name (under section 502(b)(1) of the act (21 U.S.C. 352(b)(1))) appears on the label of a nonprescription drug product marketed in the United States without an approved application.

*Burden Estimate*: FDA is requesting public comment on the estimated one-time reporting burden from these respondents, as required by 502(x) of the act and described in the guidance ''Labeling of Nonprescription Human Drug Products Marketed Without an Approved Application as Required by

the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' The estimates for one-time reporting are based on FDA's knowledge of nonprescription drug product labeling in the United States, whether or not marketed under an approved application.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

| | No. of Respondents | Frequency per Response | Total Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Domestic address or telephone number labeling requirement (21 U.S.C. 502(x)) and recommendation to clarify its purpose | 200 | 500 | 100,000 | 4 | 400,000 |

[1] There are no capital costs or maintenance and operating costs associated with this collection of information.

As indicated in Table 1 of this document, we estimate that approximately 200 manufacturers will revise approximately 100,000 labels to add a full domestic address and a domestic telephone number, and should they choose to adopt the guidance's recommendation, to add a statement identifying the purpose of the domestic address or telephone number. FDA believes that designing the label change should not take longer than 4 hours per label. Automated printing of the labels should only require a few seconds per label. This estimate accounts for the possibility that every manufacturer will make label revision, which is unlikely. Because the majority of over-the-counter drug product labels currently have a domestic telephone number that satisfies the requirement, we believe many manufacturers will opt not to adopt the guidance's recommendation to add a statement identifying the purpose of the address or telephone number, significantly reducing the number of total responses. However, assuming that all labels are revised, estimate a one-time reporting burden for this information collection of 400,000 hours.

In the **Federal Register** of January 2, 2008 (73 FR 196), FDA published a notice of availability for the original draft guidance that also gave notice of the proposed collections of information in the draft guidance, included an analysis and burden estimate for those proposed collections of information, and provided 60 days for public comment under the PRA. FDA did not revise the PRA burden analysis and estimate when it issued the revised draft guidance in December 2008 because the revisions did not affect them.

FDA received one comment on the proposed collections of information, stating that the time involved in revising labels would be significantly longer than the typical timeframe to implement labeling changes because the volume of labels required to be revised at one time might exceed manufacturers' labeling revision capacity. Several comments requested that FDA extend the date of its enforcement discretion. In response to comments, in December 2008, FDA published a notice of availability of the revised draft guidance for industry. The revised draft guidance was identical to the first draft guidance, with the exception that, in the revised draft guidance, FDA stated its intention to exercise enforcement discretion until January 1, 2010. As a result, any label revision made as a result of this guidance would likely be made contemporaneously with other scheduled label revisions, minimizing the burden to industry.

Dated: February 17, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9–3917 Filed 2–23–09; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0664]**

### Clinical Trial Design for Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia; Public Workshop

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

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Infectious Diseases Society of America (IDSA), the American College of Chest Physicians (ACCP), the Society of Critical Care Medicine (SCCM), and the American Thoracic Society (ATS) regarding scientific issues in clinical trial design for hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP). This public workshop is intended to provide information about, and gain perspective from, health care providers, academia, and industry on various aspects of antimicrobial drug development for HAP and VAP, including diagnosis of HAP and VAP, effect of antimicrobial treatment for HAP and VAP, endpoints for trials of HAP and VAP, and statistical issues in analysis of results of trials in HAP and VAP. The input from this public workshop will help in developing topics for further discussion.

*Date and Time*: The public workshop will be held on March 31, 2009, from 8 a.m. to 6 p.m. and on April 1, 2009, from 8 a.m. to 5 p.m.

*Location*: The public workshop will be held at the Crowne Plaza Hotel, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD 20910. Seating is limited and available only on a first-come, first-served basis.

*Contact*: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993– 0002, 301–796–1300.

*Registration*: To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax numbers) to *HAPwkshp@fda.hhs.gov* by March 23, 2009. Persons without access to the Internet can call 301–796–1300 to register. Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. Persons needing a sign language interpreter or other special accommodations should notify Chris Moser or Lori Benner (see Contact) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop, cosponsored with IDSA, ACCP, SCCM, and ATS, regarding antimicrobial drug