EXHIBIT 1.—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|---|---|---|---|---|
| Data entry into GRS | 500 | 3 | 10/60 | 250 |
| Total | 500 | na | na | 250 |

EXHIBIT 2.—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Total burden hours | Average hourly wage rate* | Total cost burden |
|---|---|---|---|---|
| Data entry into GRS | 500 | 250 | $30.00 | $7,500 |
| Total | 500 | 250 | na | 7,500 |

*Based upon the average wages, ''National Compensation Survey: Occupational Wages in the United States, May 2006,'' U.S. Department of Labor, Bureau of Labor Statistics.

This information collection will not impose a cost burden on the respondents beyond that associated with their time to provide the required data. There will be no additional costs for capital equipment, software, computer services, etc.

**Estimated Annual Costs to the Federal Government**

The annual cost to the government is $100,000 for licensing, support and maintenance.

**Request for Comments**

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 26, 2007.

**Carolyn M. Clancy,**

*Director.*

[FR Doc. 07–5886 Filed 11–29–07; 8:45 am]

**BILLING CODE 4160–90–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0323]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

**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 December 31, 2007.

**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 *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0045. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

**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.

**Comment Request; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution—(OMB Control Number 0910–0045—Extension)**

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the act), (21 U.S.C. 360), FDA is authorized to establish a system for registration of producers of drugs and for listing of drugs in commercial distribution. To implement section 510 of the act, FDA issued part 207 (21 CFR part 207). Under current[1] 21 CFR 207.20,

[1] This notice requests comments on the information collection in current part 207. In the **Federal Register** of August 29, 2006 (71 FR 51276), FDA proposed to revise part 207. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list, and describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally also require the electronic submission of all registration and most listing information. The August 29, 2006, proposed rule requested comments on the information collection for revised part 207. When the proposal is finalized, the

Continued

manufacturers, repackers, and relabelers that engage in the manufacture, preparation, propagation, compounding, or processing of human or veterinary drugs and biological products, including bulk drug substances and bulk drug substances for prescription compounding, and drug premixes as well as finished dosage forms, whether prescription or over-the-counter, are required to register their establishment. In addition, manufacturers, repackers, and relabelers are required to submit a listing of every drug or biological product in commercial distribution. Owners or operators of establishments that distribute, under their own label or trade name, a drug product manufactured by a registered establishment are not required either to register or list. However, distributors may elect to submit drug listing information in lieu of the registered establishment that manufactures the drug product. Foreign drug establishments must also comply with the establishment registration and product listing requirements if they import or offer for import their products into the United States.

Under current §§ 207.21 and 207.22, establishments, both domestic and foreign, must register with FDA by submitting Form FDA–2656 (Registration of Drug Establishment) within 5 days after beginning the manufacture of drugs or biologicals, or within 5 days after the submission of a drug application or biological license application. In addition, establishments must register annually by returning, within 30 days of receipt from FDA, Form FDA–2656e (Annual Update of Drug Establishment) (Note: This form is no longer mailed to registrants by FDA; updating registration information is estimated in the table in this document by the information submitted annually on Form FDA–2656). Changes in individual ownership, corporate or partnership structure, location, or drug-handling activity must be submitted as amendments to registration under current § 207.26 within 5 days of such changes. Distributors that elect to submit drug listing information must submit a Form FDA–2656 to FDA and a copy of the completed form to the registered establishment that manufactured the product to obtain a labeler code. Establishments must, within 5 days of beginning the manufacture of drugs or biologicals, submit to FDA a listing for every drug or biological product in commercial distribution at that time by using Form FDA–2657 (Drug Product Listing). Private label distributors may elect to submit to FDA a listing of every drug product they place in commercial distribution. Registered establishments must submit to FDA drug product listing for those private label distributors who do not elect to submit listing information by using Form FDA–2658 (Registered Establishments' Report of Private Label Distributors).

Under current § 207.25, product listing information submitted to FDA by domestic and foreign manufacturers must, depending on the type of product being listed, include any new drug application number or biological establishment license number, copies of current labeling and a sampling of advertisements, a quantitative listing of the active ingredient for each drug or biological product not subject to an approved application or license, the National Drug Code number, and any drug imprinting information.

In addition to the product listing information required on Form FDA–2657, FDA may also require, under current § 207.31, a copy of all advertisements and a quantitative listing of all ingredients for each listed drug or biological product not subject to an approved application or license; the basis for a determination, by the establishment, that a listed drug or biological product is not subject to marketing or licensing approval requirements; and a list of certain drugs or biological products containing a particular ingredient. FDA may also request, but not require, the submission of a qualitative listing of the inactive ingredients for all listed drugs or biological products, and a quantitative listing of the active ingredients for all listed drugs or biological products subject to an approved application or license.

Under current § 207.30, establishments must update their product listing information by using Form FDA–2657 and/or Form FDA–2658 every June and December or, at the discretion of the establishment, when any change occurs. These updates must include the following information: (1) A listing of all drug or biological products introduced for commercial distribution that have not been included in any previously submitted list; (2) all drug or biological products formerly listed for which commercial distribution has been discontinued; (3) all drug or biological products for which a notice of discontinuance was submitted and for which commercial distribution has been resumed; and (4) any material change in any information previously submitted. No update is required if no changes have occurred since the previously submitted list.

In the **Federal Register** of August 24, 2007 (72 FR 48656), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the annual information collection burden for current part 207 as follows:

| Form | Number of Respondents | Number of Responses Per Respondent | Total Annual Responses | Hours Per Responses | Total Hours |
|---|---|---|---|---|---|
| (1) *Form FDA–2656—Registration of Drug Establishment* (New registrations, including new labeler codes for private label distributors) | 39 | 14.72 | 574 | 2.50 | 1,435 |
| (2) *Form FDA–2656—Annual Update of Drug Establishment* (Update of registration information) | 3,256 | 2.99 | 9,763 | 2.50 | 24,407.50 |
| (3) *Form FDA–2657—Drug Product Listing* (New drug listings) | 1,567 | 6.57 | 10,301 | 2.50 | 25,752.50 |
| (4) *Form FDA–2658—Registered Establishments' Report of Private Label Distributors* (New listings for private label distributor drugs) | 146 | 10.06 | 1,469 | 2.50 | 3,672.50 |

information collection for revised part 207 will replace the information collection in this notice.

| Form | Number of Respondents | Number of Responses Per Respondent | Total Annual Responses | Hours Per Responses | Total Hours |
|---|---|---|---|---|---|
| (5) *Form FDA–2657 and Form FDA–2658*—(June and December updates of all listing information) | 1,677 | 11.21 | 18,797 | 2.50 | 46,992.50 |
| Total | | | | | 102,260 |

Dated: November 27, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–23275 Filed 11–29–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2007N–0277]**

## Food Labeling: Use of Symbols to Communicate Nutrition Information, Consideration of Consumer Studies and Nutritional Criteria; Reopening of Comment Period

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

**ACTION:** Notice of public hearing; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening to January 15, 2008, the comment period for the notice of public hearing that published in the **Federal Register** of July 20, 2007. In the notice of public hearing, FDA requested comments on the use of symbols to communicate nutrition information on food labels. The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

**DATES:** Submit written or electronic comments by January 15, 2008.

**ADDRESSES:** You may submit comments, identified by Docket No. 2007N–0277, by any of the following methods:

*Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

*Written Submissions*

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously in the **ADDRESSES** portion of this document under *Electronic Submissions* .

*Instructions*: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Request for Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket*: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Juanita Yates, Center for Food Safety and Applied Nutrition (HFS–555), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1731.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In the **Federal Register** of July 20, 2007 (72 FR 39815), FDA published a notice of public hearing with a 115-day comment period to request comments on the use of symbols to communicate nutrition information on food labels, specifically, the issues and questions presented in section III of the notice (see 72 FR 39815 at 39816). Comments will inform FDA's consideration of the use of symbols to communicate nutrition information on food labels.

The agency has received a request for a 60-day extension of the comment period for the notice of public hearing. The request conveyed concern that the comment period, which closed 60 days subsequent to the public hearing held September 10 and 11, 2007, did not allow sufficient time to develop a meaningful or thoughtful response to the request for comments on the issues and questions presented in section III of the notice.

FDA has considered the request and is reopening the comment period for the notice of public hearing, which closed November 12, 2007, for 60 days, until January 15, 2008. The agency believes that reopening the comment period for 60 days allows adequate time for interested persons to submit comments on the issues and questions presented in section III of the notice without significantly delaying the agency's consideration of the use of symbols to communicate nutrition information on food labels.

### II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: November 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7–23211 Filed 11–29–07; 8:45 am]

**BILLING CODE 4160–01–S**