

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[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 *[insert date 30 days after date of publication in the Federal Register]*.

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 current¹ 21 CFR 207.20, 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

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

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) <i>Form FDA-2656—Registration of Drug Establishment (New registrations, including new labeler codes for private label distributors)</i>	39	14.72	574	2.50	1,435
(2) <i>Form FDA-2656—Annual Update of Drug Establishment (Update of registration information)</i>	3,256	2.99	9,763	2.50	24,407.50
(3) <i>Form FDA-2657—Drug Product Listing (New drug listings)</i>	1,567	6.57	10,301	2.50	25,752.50
(4) <i>Form FDA-2658—Registered Establishments' Report of Private Label Distributors (New listings for private label distributor drugs)</i>	146	10.06	1,469	2.50	3,672.50
(5) <i>Form FDA-2657 and Form FDA-2658—(June and December updates of all listing information)</i>	1,677	11.21	18,797	2.50	46,992.50
Total					102,260

Dated: NOV 27 2007
November 27, 2007.

Jeffrey Shuren
Jeffrey Shuren,
Assistant Commissioner for Policy.

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Suzette Rose