

postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4) and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

Description of Respondents: The recordkeeping and reporting recommendations described in this document affect the participating licensed manufacturer(s), final product manufacturer(s), and contract manufacturer(s) associated with cooperative manufacturing arrangements.

Burden Estimate: We believe that the information collection provisions in the guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practices. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

The guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, and 807, 809, and 820 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820). The collections of information in §§ 606.121, 606.122, and 610.40 have been approved under OMB control number 0910-0116; § 610.2 has been approved under OMB control number 0910-0206; §§ 600.12(e) and 600.80 have been approved under OMB control number 0910-0308; §§ 601.2(a), 601.12, 610.60 through 610.65, 610.67, 660.2(c), 660.28(a) and (b), 660.35(a), (c) through (g), and (i) through (m), 660.45, and 660.55(a) and (b) have been approved under OMB control number 0910-0338; §§ 803.20, 803.50, and 803.53 have been approved under OMB control number 0910-0437; and §§ 600.14 and 606.171 have been approved under OMB control number 0910-0458. The current good manufacturing practice regulations for finished pharmaceuticals (part 211) have been approved under OMB control number 0910-0139; §§ 820.181 and 820.184 have been approved under OMB control number 0910-0073; the establishment registration regulations (parts 207, 607, and 807) have been approved under OMB control numbers

0910-0045, 0910-0052, and 0910-0387; and the labeling regulations (parts 201, 801, and 809) have been approved under OMB control numbers 0910-0537, 0910-0572, and 0910-0485.

In the **Federal Register** of March 16, 2011 (76 FR 14405), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received from the public.

Dated: August 2, 2011.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0508]

Agency Information Collection Activities; Proposed Collection; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the blood establishment registration and product listing requirements in the Agency's regulations and Form FDA 2830.

DATES: Submit either electronic or written comments on the collection of information by October 7, 2011.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607—(OMB Control Number 0910-0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business, and all such establishments, and must submit, among other

information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a), in brief, requires owners or operators of certain establishments that engage in the manufacture of blood products to register and to submit a list of every blood product in commercial distribution. Section 607.21, in brief, requires the owners or operators of establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation for which a license is required, registration must follow within 5 days after the submission of a biologics license application. In addition, owners or operators of all establishments so engaged must register annually between

November 15 and December 31 and must update their blood product listing information every June and December. Section 607.22 requires the use of Form FDA 2830 (Blood Establishment Registration and Product Listing) for initial registration, subsequent annual registration, and for blood product listing information. Section 607.25 sets forth the information required for establishment registration and blood product listing. Section 607.26, in brief, requires certain changes to be submitted on Form FDA 2830 as an amendment to establishment registration within 5 days of such changes. Section 607.30(a), in brief, sets forth the information required from owners or operators of establishments when updating their blood product listing information every June and December, or at the discretion of the registrant at the time the change occurs. Section 607.31 requires that additional blood product listing information be provided upon FDA request. Section 607.40, in brief, requires certain foreign blood product establishments to comply with the establishment registration and blood product listing information requirements discussed above and to

provide the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's blood supply. Form FDA 2830 is used to collect this information.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon information obtained from FDA's Center for Biologics Evaluation and Research's database and FDA experience with the blood establishment registration and product listing requirements.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Form FDA 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
607.20(a), 607.21, 607.22, 607.25, and 607.40.	Initial Registration	49	1	49	1	49
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.	Re-registration	2,589	1	2,589	0.5	1,294
607.21, 607.25, 607.30(a), 607.31, and 607.40.	Product Listing Update	180	1	180	0.25	45
Total	1,388

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

Dated: July 26, 2011.
David Dorsey,
Acting Deputy Commissioner for Policy, Planning and Budget.
 [FR Doc. 2011-19955 Filed 8-5-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0126]

Andrew K. Choi: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarment Andrew K. Choi, M.D. for 4 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on findings that Dr. Choi was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Dr. Choi was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Choi failed to respond. Dr. Choi's failure

to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 8, 2011.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-4640.

SUPPLEMENTARY INFORMATION: