Dated: December 16, 2011.

Leslie Kux,  
Acting Assistant Commissioner for Policy.

[FR Doc. 2011–32776 Filed 12–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0508]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Blood Establishment Registration and Product Listing, Food and Drug Administration Form 2830

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 January 23, 2012.

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) 395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0052. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, (301) 796–7726, Ila.Mizrachi@fda.hhs.gov.

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.

Blood Establishment Registration and Product Listing, FDA Form 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 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 FDA Form 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 FDA Form 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 earlier in this document 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. FDA Form 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.

In the Federal Register of August 8, 2011 (76 FR 48167), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>FDA Form 2830</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>607.20(a), 607.21, 607.22, 607.25, and 607.40.</td>
<td>Initial registration</td>
<td>49</td>
<td>1</td>
<td>49</td>
<td>1</td>
<td>49</td>
</tr>
<tr>
<td>607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.</td>
<td>Re-registration</td>
<td>2,589</td>
<td>1</td>
<td>2,589</td>
<td>0.5</td>
<td>1,295</td>
</tr>
</tbody>
</table>
### 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.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and “Lookback”—(OMB Control Number 0910–0116)—Extension

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 351(a) of the PHS Act requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into injectable products, have a license, issued upon a demonstration that the product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic Act also applies to biological products. Blood and blood components for transfusion or for further manufacture into injectable products are drugs, as that term is defined in section 201(g)(1) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the Federal, Food, Drug, and Cosmetics Act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the Act. For example, under section 501 of the

### TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1—Continued

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>FDA Form</th>
<th>Number of responses</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>607.21, 607.25, 607.30(a), 607.31, and 607.40.</td>
<td>Product listing update</td>
<td>180</td>
<td>1</td>
<td>180</td>
<td>0.25 (15 min.)</td>
<td>45</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,389</td>
</tr>
</tbody>
</table>

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