The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 24, 1999.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–22988 Filed 9–2–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2875]

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 provisions relating to the blood establishment registration and product listing requirements in 21 CFR part 607 and relating to Form FDA 2830.

DATES: Submit written comments on the collection of information by November 2, 1999.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 request 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 listed below.

With respect to the following collection of information, FDA invites comments on: (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 (the 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 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) requires certain establishments that engage in the manufacture of blood products to register and to submit a list of blood product in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a blood product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their blood product listing every June and December. Section 607.22 requires the use of Form FDA 2830 for registration and blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires for certain changes an amendment to the establishment registration to be made within 5 days of such changes. Section 607.30 requires establishments to update, as needed, their blood product listing information every June and at the annual registration. Section 607.31 requires that additional blood product listing information be provided upon FDA request.

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, Blood Establishment Registration and Product Listing, is used to collect this information. The likely respondents are blood banks, blood collection facilities, and blood component manufacturing facilities.

FDA estimates the burden of this collection of information based upon the past experience of the Center for Biologics Evaluation and Research, Division of Blood Applications, in regulatory blood establishment registration and product listing. Most blood banks are familiar with the regulations and registration requirements to fill out this form.

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	Form FDA 2830	No. Of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, 607.25	Initial Registration	300	1	300	1	300
607.21,607.22, 607.25, 607.26, 607.31	Re-registration	3,300	1	3,300	0.5	1,650
607.21, 607.25, 607.30, 607.31	Product Listing Update	75	1	75	0.25	19
Total						1,969

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

Dated: August 27, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–23002 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–2799]

SteriGenics International, Inc.; Filing of Food Additive Petition (Animal Use); Irradiation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that SteriGenics International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the approval to irradiate various animal feeds and feed ingredients for microbial control.

DATES: Written comments on the petitioner's environmental assessment by November 2, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John D. McCurdy, Center for Veterinary Medicine (HFV–222), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0171.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 2243) has been filed by SteriGenics International, Inc., 4020 Clipper Ct., Fremont, CA 94538–6540. The petition proposes to amend the food additive regulations on irradiation in the production, processing, and handling of animal feed and pet food in 21 CFR part 579 to approve irradiation in various animal feeds and feed ingredients for microbial control.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment.

Interested persons may, on or before November 2, 1999, submit to the Dockets Management Branch written comments. Two copies of any comments are to be submitted, except that individuals may submit one 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, FDA finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: August 25, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–22999 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2729]

Draft Guidance for Industry on BA and BE Studies for Orally Administered Drug Products—General Considerations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''BA and BE Studies for Orally Administered Drug Products—General Considerations.'' This draft guidance provides recommendations to sponsors and applicants intending to submit bioavailability (BA) and/or bioequivalence (BE) information in investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and their amendments and supplements, to the Center for Drug Evaluation and Research (CDER). This draft guidance provides general information on how to comply with the BA and BE requirements for orally administered dosage forms in 21 CFR part 320. It is one of a set of planned core guidances designed to reduce and/or eliminate the need for FDA drug-specific BA/BE guidances.

DATES: Written comments on the draft guidance document may be submitted by November 2, 1999. Interested parties are invited to submit information specifically to support or refute some of the approaches in the draft guidance that are intended to reduce regulatory burden. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for