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

single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: 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 provide BA and BE information in IND's, NDA's, ANDA's, and their amendments and supplements that complies with the BA and BE requirements in 21 CFR part 320 as they apply to dosage forms intended for oral administration.

This draft guidance focuses primarily on product quality BA and BE. Product quality BA encompasses information related to release of the drug substance from the drug product into systemic circulation. BE is a formal comparative test that uses: (1) Specified criteria for comparisons, (2) BE limits (goal posts), and (3) confidence intervals to determine if the observed interval falls within the specified limit.

Many aspects of this draft guidance represent departures from past practices used to document BE. Although some aspects of this draft guidance may result in small increases of regulatory burden, the main intent of many of these changes is to reduce the regulatory burden while maintaining sound scientific principles consistent with public health objectives. Specific examples of reduction of the regulatory burden include: (1) Enable biowaivers for lower strengths of modified release dosage forms, (2) eliminate multiple dose BE studies for modified release dosage forms, (3) enable biowaivers for higher strength of immediate release dosage forms, and (4) reduce emphasis on measuring metabolites in BE studies. Respondents to the **Federal Register** notice are encouraged to provide data that can be used to support or refute proposals in the draft guidance.

In the past, BE studies have been performed as single-dose, crossover studies in healthy volunteers. To compare measures in these studies, data have been analyzed using an average BE criterion. In this draft guidance, FDA recommends the use of new criteria to allow comparison of BE. One, termed an individual BE criterion, means having study designs in which both the test and reference drug products are administered to the same individuals on two separate occasions (replicate study designs). Another, termed a population BE criterion, does not involve replicate study designs. The individual BE is recommended for use in in vivo BE studies submitted in: (1) ANDA's, and (2) NDA's and ANDA's when the need to redocument BE arises after approval. The population BE criterion is recommended for use by sponsors who conduct certain important in vivo BE studies (e.g., studies that compare clinical trial material with the to-be-marketed dose form). The use of the proposed individual BE criterion is based on the assessment of both means and variances of BA measures, to include a subject-by-formulation (S*F) interaction variance and within-subject variance for both test and reference products. Both population and individual criteria allow scaling of the BE limit according to variability of the reference product.

FDA has expended substantial effort in determining whether S*F interaction and increased within-subject variability occur with sufficient frequency to affect a conclusion of switchability between test and reference products. FDA believes that additional information on the frequency and the magnitude of the different variance terms, as well as other information, is needed. For this reason, this draft guidance is recommending that sponsors conduct all in vivo BE studies for: (1) IND's, (2) NDA's, (3) ANDA's, and (4) amendments and supplements to NDA's and ANDA's using replicate designs for a 2-year period following the publication of the final version of this guidance. For example, the current average BE criteria generally require 24 subjects in a two-period study design (total of 24 x 2 = 48 dosage administrations). The proposed replicate study design would require 12 subjects in a four-period study (total of 12 x 2 x 2 dosage administrations). However, there is no increase in total number of dosage administrations to be analyzed. Sponsors can analyze their data using either average or population criteria (IND's and NDA's) or average or individual criteria (ANDA's and supplements to NDA's and ANDA's). Sponsors should specify their choice in the study protocol submitted to the appropriate institutional review board prior to study initiation. At the sponsor's discretion, scaling may be used, under certain circumstances, to judge BE when either an individual or population criterion is specified. Because data from the recommended replicate studies may be powered for an average BE criterion, the burden of performing replicate BE studies is minimized. The agency in turn will perform individual BE analyses on all submitted data to determine subject x formulation interactions. Information from these studies will enable FDA to assess further the usefulness of the proposed individual and population BE criteria.

This draft guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on bioavailability and bioequivalence studies for orally administered drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23009 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

AIDS Education and Training Centers Evaluation Center Grant

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Availability of Funds.

SUMMARY: The Health Resources and Services Administration's (HRSA) HIV/