TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1140.32	1	1	1	1	1

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

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding pharmaceutical advertising and cigarette and smokeless tobacco product advertising expenditures. The burden collection does not include reporting burdens associated with providing established names on labels and statements of intended use because section 102 of the Tobacco Control Act required that these provisions be struck from the reissued final rule (previously included in §§ 897.24 and 897.32(c)).

Section 1140.30 requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising. FDA estimates that approximately 300 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice.

For the recordkeeping and disclosure requirements, § 1140.32 requires competent and reliable survey evidence to establish whether a newspaper, magazine, periodical, or other publication qualifies as an ''adult'' publication. Section 1140.32 also requires the use of a black text on a white background for labeling and advertising. The respondent and hourly burden for recordkeeping and disclosure under this section (2 burden hours total) reflect placeholders for the number of manufacturers who would keep records under this section.

During the next 3 years, FDA does not intend to enforce the recordkeeping and disclosure requirements of § 1140.32 and has revised the burden to act as a placeholder in the event FDA exercises its authority to enforce the requirements of this section in the future.

FDA estimates that the total time required for this collection of information is 302 hours.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08034 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0248]

Center for Biologics Evaluation and Research eSubmitter Pilot Evaluation Program for Investigational New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is announcing an invitation to sponsors of investigational new drug (IND) applications to participate in a pilot evaluation program for CBER's eSubmitter Program (eSubmitter). CBER's eSubmitter is a computer-assisted automated program that has been customized to facilitate the creation of IND applications in electronic format, including a template specifically for IND applications related to antivenom drugs/antivenins. Participation in the pilot program is open to sponsors that submit IND applications to the Office of Blood Research and Review, the Office of Cellular, Tissue and Gene Therapy, or the Office of Vaccines Research and Review in CBER. CBER will only accept participation from up to nine sponsors. The pilot program is intended to provide industry and CBER regulatory review staff with an opportunity to evaluate the eSubmitter system and determine if it facilitates the IND submission process. The purpose of this notice is to invite sponsors of IND applications to contact CBER for more information if they are interested in participating in this pilot program.

DATES: Submit an electronic request for participation in this program by July 8, 2013.

ADDRESSES: If you are interested in participating in this program, you should submit an electronic request to *CBER_eSubmitter_program@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Lore Fields, Office of Blood Research and Review, Center for Biologics Evaluation and Research (HFM–375), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6143, FAX: 301–827–3534, email: *lore.fields@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and timely delivery of these products to patients. Further, CBER seeks to continuously enhance and update the efficiency and quality of its regulatory review process and to facilitate its interaction with stakeholders by providing CBER staff and industry with improved processes. In support of this goal, CBER has participated in FDA's development of eSubmitter to improve the process for providing certain regulatory submissions to FDA.

II. eSubmitter Pilot Evaluation Program Expectations

The eSubmitter pilot evaluation program is expected to last approximately 6 months. During this period of time, participants will complete their IND application submissions using the eSubmitter template developed by FDA that has been specifically designed for use by IND sponsors. eSubmitter was developed using the same criteria for applications that are currently used in the IND application review process at CBER. To create the IND application, the participant will enter the requested information into the eSubmitter tool and attach requested documents as an Adobe document (pdf format). This information will be saved onto a CD–ROM by the sponsor and mailed to CBER for review. Paper copies of submissions will not be required. CBER will review the information provided on

the CD–ROM and the attachments according to current managed review procedures. Only new IND applications and their amendments will be eligible for participation in the pilot program.

During the IND application process, CBER staff will be available to answer any questions or concerns that may arise. As each application is completed, the users will be asked to comment on the eSubmitter program. These comments and discussions will assist CBER in the final development and release of this electronic program for use by industry.

III. Requests for Participation

Requests to participate in the eSubmitter Pilot Evaluation Program should be sent electronically to *CBER_eSubmitter_program @fda.hhs.gov.* You should include the following information in your request: Contact name, contact phone number, email address, name of the facility, address, and registration number (if applicable). Once requests for participation are received, FDA will contact interested sponsors to discuss the pilot program.

Dated: April 2, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–08012 Filed 4–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by June 7, 2013.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kris André, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** of December 17, 2012 (77 FR 74669). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

A

Albuterol sulfate (multiple RLDs)
Amoxicillin

C

Cefixime

D

Desipramine hydrochloride
Desvenlafaxine
Dutasteride; tamsulosin hydrochloride

E

Estramustine phosphate sodium
Ethinyl estradiol, etonogestrel
Ethionamide
Ezogabine

F

Flutamide

H

Hydrocortisone

I

Icosapent ethyl

K

Ketorolac tromethamine

L

Loratadine

M

Miconazole
Minocycline hydrochloride
Mitotane

N

Nevirapine

P

Phentermine hydrochloride; topiramate

R

Rimexolone
Rizatriptan benzoate