

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Activity	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Mandatory and Voluntary RFR Reports via the SRP.	3800	1,413	1	1,413	0.6 (36 minutes)	848
Total	897,129

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

The Agency's estimate of the number of respondents and the total annual responses in table 2, Estimated Annual Reporting Burden, is based primarily on mandatory and voluntary adverse event reports electronically submitted to the Agency. The estimated total annual responses are based on initial reports. Follow-up reports, if any, are not counted as new reports. Based on its experience with adverse event reporting, FDA estimates that it will take a respondent 0.6 hour to submit a voluntary adverse event report via the SRP, 1.0 hour to submit a mandatory adverse event report via the SRP, and 0.6 hour to submit a mandatory adverse event report via the ESG (gateway-to-gateway transmission). Both mandatory and voluntary RFR reports must be submitted via the SRP. FDA estimates that it will take a respondent 0.6 hour to submit a RFR report, whether the submission is mandatory or voluntary.

Voluntary adverse event reports submitted via the SRP (other than RFR Reports) include reports associated with pet food (the Pet Food Early Warning System) and the new tobacco product adverse event and product problem reports. CVM received 845 pet food adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,413 reports. Based on this experience, CVM estimates that it will receive, on average, 1,413 pet food reports annually over the next 3 years. CTP estimates that it will receive approximately 100 voluntary tobacco product adverse event and product problem reports annually, after implementation of electronic reporting. CTP received 27 reports in 2010, 30 reports in 2011, and 22 reports in the first half of 2012, and estimates that for the full 12 months of 2012 it will receive over 40 reports. Based on this experience and an expectation that reporting will increase once electronic reporting is launched, CTP estimates that it will receive, on average, 100 voluntary adverse event and product problem reports annually over the next 3 years. Thus, FDA estimates that over

the next 3 years it will receive annually 1,513 voluntary adverse event reports submitted via the SRP, with a burden of 907.8 hours, rounded to 908 hours, as reported in table 2, row 1 (1,413 + 100 = 1,513).

Mandatory adverse event reports submitted via the SRP (other than RFR Reports) include reports of adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. CVM received 144 such adverse event reports in 2010, 537 reports in 2011, and 212 reports in the first 4 months of 2012, and estimates that for the full 12 months of 2012 it will receive 636 reports. Based on this experience, CVM estimates that it will receive, on average, 636 reports of adverse drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs annually over the next 3 years. Thus, FDA estimates that over the next 3 years it will receive annually 636 mandatory adverse event reports submitted via the SRP, with a burden of 636 hours, as reported in table 2, row 2.

Adverse event reports submitted via the ESG include reports of adverse experiences related to drugs, biological products, and medical devices, as well as, adverse animal drug experiences and product/manufacturing defects associated with approved NADAs and ANADAs. FDA received 586,229 such adverse event reports in 2010; 850,161 reports in 2011; and 497,076 reports in the first 4 months of 2012; and estimates that for the full 12 months of 2012 it will receive 1,491,228 reports. Based on this experience, FDA estimates that it will receive, on average, 1,491,228 adverse event reports submitted via the ESG, with a burden of 894,736.8 hours, rounded to 894,737 hours, as reported in table 2, row 3.

FDA estimates that over the next 3 years it will receive annually 1,413 mandatory and voluntary RFR Reports submitted via the SRP, as reported in table 2, row 4. CFSAN received 845 such adverse event reports in 2010; 1,293 reports in 2011; and 471 reports in the first 4 months of 2012; and estimates that for the full 12 months of

2012 it will receive 1,413 reports. Based on this experience, CFSAN estimates that it will receive, on average, 1,413 mandatory and voluntary RFR Reports submitted via the SRP annually over the next 3 years, with a burden of 847.8 hours, rounded to 848 hours, as reported in table 2, row 4.

The burden hours required to complete paper FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are reported under OMB control numbers 0910-0284 and 0910-0291.

While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from \$20 to \$30.

Dated: August 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369 (formerly Docket 2007D-0168)]

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, 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 November 13, 2012.

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: K. Geoffrey Wu, 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/GuidanceComplianceRegulatoryInformation/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 June 14, 2012 (77 FR 35688). 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

Amoxicillin
Amoxicillin; clavulanate potassium
Amphetamine aspartate; amphetamine sulfate; dextroamphetamine saccharate; dextroamphetamine sulfate

B

Budesonide
Bupropion hydrochloride (multiple reference listed drugs (RLDs))

C

Calcitonin salmon
Carbidopa; levodopa
Carglumic acid
Ciclesonide
Ciprofloxacin; dexamethasone
Cyclophosphamide

D

Dalteparin sodium

E

Estramustine phosphate sodium

F

Fentanyl citrate

K

Ketoconazole

L

Linagliptin

M

Mesalamine (multiple RLDs and dosage forms)
Methylphenidate hydrochloride (multiple RLDs)

N

Nifedipine

O

Omega-3-acid ethyl esters
Omeprazole

P

Paclitaxel
Pazopanib hydrochloride
Progesterone

R

Rilpivirine hydrochloride
Roflumilast

S

Saxagliptin hydrochloride

T

Telaprevir
Tenofovir disoproxil fumarate
Thioguanine
Thalidomide
Tretinoin (multiple RLDs and dosage forms)

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

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

A

Azacitidine
Azelaic acid

C

Capecitabine

E

Estrogen, esterified
Etravirine

H

Hydrochlorothiazide; losartan potassium

L

Lopinavir; ritonavir

P

Phytonadione (multiple RLDs and dosage forms)
Propranolol hydrochloride

S

Sapropterin dihydrochloride
Sumatriptan

T

Tadalafil
Theophylline (multiple RLDs)
Tolterodine tartrate
Topiramate
Trazodone hydrochloride

For a complete history of previously published **Federal Register** notices related to product-specific BE recommendations, please go to <http://www.regulations.gov> and enter docket number FDA-2007-D-0369.

These draft and revised draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). These guidances represent the Agency’s current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An

alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidances, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 4, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Process Evaluation of the Early Independence Award (EIA) Program

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of Strategic Coordination (OSC), Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 13, 2012 (Vol. 77, No 114, Page 35408), and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Process Evaluation of the Early Independence

Award (EIA) Program. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will assess the EIA program operations. The primary objectives of the study are to: (1) Assess if the Requests for Applications (RFAs) are meeting the needs of applicants; (2) document the selection process; (3) document EIA program operations; (4) assess the progress being made by the Early Independence Principal Investigators; and (5) assess the support provided by the Host Institutions to the Early Independence Principal Investigators. The findings will provide valuable information concerning: (1) Aspects of the program that could be revised or improved; (2) progress made by the Early Independence Principal Investigators; and (3) implementation of the program at Host Institutions. *Frequency of Response:* On occasion. *Affected Public:* None. *Type of Respondents:* Applicants, reviewers, and awardees. The annual reporting burden is as follows: *Estimated Number of Respondents:* 390; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* .4; and *Estimated Total Annual Burden Hours Requested:* 158. The annualized cost to respondents is estimated at \$9,774. There are no Capital Costs to report.

A.12.1—ANNUALIZED ESTIMATE OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response (in hrs.)	Annual hour burden
Editorial Board Reviewers (paper survey)	15	1	15/60	4
Applicants—Junior Scientists (online survey)	150	1	15/60	38
Applicants—Officials of Host Institutions (online survey)	150	1	15/60	38
Awardees—Early Independence Principal Investigator (paper survey—beginning of 1st year of award)	12	1	30/60	6
Awardees—Early Independence Principal Investigator (phone interview—end of 1st year of award)	12	1	1	12
Awardees—Early Independence Principal Investigator (online survey—end of 2nd and 3rd year of award)	24	1	1	24
Awardees—Point of Contact at Host Institution (phone interview—end of 1st year of award)	12	1	1	12
Awardees—Point of Contact at Host Institution (online survey—end of 2nd and 3rd year of award)	24	1	1	24
Total				158

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have

practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those

who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and