TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR Section | Form FDA No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|---|
| 601.2(a),[2] 610.60 through 610.65[3] | 2567/356h | 25 | 1.8 | 45 | 860 | 38,700 |
| 601.5(a) | NA | 8 | 1 | 8 | *0.33 | 2.64 |
| 601.6(a) | NA | 1 | 1 | 1 | *0.33 | 0.33 |
| 601.12(a)(5) | NA | 791 | 16.51 | 13,057 | 1 | 13,057 |
| 601.12(b)(1)/(b)(3)/(e)[4] | [2]356h | 174 | 4.01 | 698 | 80 | 55,840 |
| 601.12(c)(1)/(c)(3)[5] | [2]356h | 117 | 4.60 | 538 | 50 | 26,900 |
| 601.12(c)(5) | [2]356h | 18 | 1.61 | 29 | 50 | 1,450 |
| 601.12(d)(1)/(d)(3)[6]/(f)(3)[8] | [2]356h | 241 | 3.08 | 742 | 24 | 17,808 |
| 601.12(f)(1)[7] | 2567 | 67 | 2.48 | 166 | 40 | 6,640 |
| 601.12(f)(2)[7] | 2567 | 72 | 1.78 | 128 | 20 | 2,560 |
| 601.12(f)(4)/601.45[9] | 2567/2253 | 102 | 103.71 | 10,578 | 10 | 105,780 |
| 601.26(f) | NA | 1 | 1 | 1 | 1 | 1 |
| 601.27(b) | NA | 4 | 1 | 4 | 24 | 96 |
| 601.27(c) | NA | 6 | 1 | 6 | 8 | 48 |
| 601.70(b) and (d)/601.28 | 2252 | 56 | 1.91 | 107 | 24 | 2,568 |
| 610.15(d) | NA | 1 | 1 | 1 | 1 | 1 |
| 680.1(c) | NA | 9 | 1 | 9 | 2 | 18 |
| 680.1(b)(3)(iv) | NA | 1 | 1 | 1 | 2 | 2 |
| Amendments/Resubmissions | 356h | 207 | 12.87 | 2,664 | 20 | 53,280 |
| Total | | | | | | 324,752 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.9(a), 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3] The reporting requirements under §§ 601.93(b)(3), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a), (b), and (c), 660.35(a), (c through g), and (i through m), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.65.
[4] The reporting requirements under §§ 601.12(a)(2) and (b)(4), 600.15(b), 610.9(a), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).
[5] The reporting requirements under §§ 601.12(a)(2), 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.12(a)(2) is included in the estimate under § 601.12(d).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).
[8] The reporting requirement under §§ 601.12(a)(4) and 601.14 is included in the estimate under § 601.12(f)(3).
[9] The reporting requirement under § 601.94 is included in the estimate under § 601.45.
* 20 minutes.

Under table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

| 21 CFR Section | Number of respondents | Annual disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| 601.6(a) | 1 | 20 | 20 | *0.33 | 6.6 |

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

Dated: June 6, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–13896 Filed 6–11–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0653]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs; Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

**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 procedures by which sponsors of orphan drugs may request eligibility for the incentives by implementing a program as outlined in the Orphan Drug Act and the joint adoption by FDA and the European Medicines Agency (EMA) of the Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671).

**DATES:** Submit either electronic or written comments on the collection of information by August 12, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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:** Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov*.

**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 requests 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

**Orphan Drugs; Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671)—21 CFR Part 316 (OMB Control Number 0910–0167)—Extension**

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs; (2) designate eligible drugs as orphan drugs; (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval; and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the FD&C Act and sets forth procedures FDA will use in administering the FD&C Act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the non-clinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Based on past experience, FDA estimates that there will be two respondents to §§ 316.10, 316.12, and 316.14 requiring 200 hours of human resources annually.

Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.21 specifies content of a request for orphan drug designation required for verification of orphan-drug status. Section 316.26 allows an applicant to amend the applications under certain circumstances. The Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States and the European Union mandated by the Transatlantic Economic Council. FDA does not believe the new form will result in any increased burden on the respondents and therefore we estimate no additional burden. Based on past experience, FDA estimates there will be 214 respondents requiring 64,200 hours of human resources annually. Section 316.22 specifies requirement of a permanent resident agent for foreign sponsors. Based on past experience, FDA estimates 55 respondents requiring 110 hours of human resources annually. Section 316.27 specifies content of a change in ownership of orphan-drug designation. Based on past experience, FDA estimates 43 respondents requiring 215 hours of human resources annually. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. Based on number of orphan-drug designations, the number of respondents is estimated as 1,652 requiring 4,956 hours of human resources annually. Finally, § 316.36 describes information required of sponsor when there is insufficient quantity of approved orphan drug. Based on past experience, FDA estimates 1 respondent requiring 45 hours of human resources annually.

The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR Section and Form FDA | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Content and format when seeking written recommendations; results of studies; amendments (§§ 316.10, 316.12, 316.14) | 2 | 1 | 2 | 100 | 200 |
| Content and format of a request for orphan-drug designation; request for verification of orphan-drug status; amendments (§§ 316.20, 316.21, 316.26) Form FDA 3671 | 214 | 2 | 428 | 150 | 64,200 |
| Notifications of changes in agents (§ 316.22) | 55 | 1 | 55 | 2 | 110 |
| Submissions to change ownership of orphan-drug designation (§ 316.27) | 43 | 1 | 43 | 5 | 215 |
| Annual reports (§ 316.30) | 1,652 | 1 | 1,652 | 3 | 4,956 |
| Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug (§ 316.36) | 1 | 3 | 3 | 15 | 45 |
| Total | | | | | 69,726 |

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

Dated: June 5, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–13858 Filed 6–11–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0618]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Products

**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 information collection requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

**DATES:** Submit either electronic or written comments on the collection of information by August 12, 2013.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

**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 requests 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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

**Electronic Products—21 CFR Parts 1002 Through 1010 (OMB Control Number 0910–0025)—Extension**

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in title 21 of the Code of Federal Regulations, chapter I, subpart J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of the Department of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act authorizes the Secretary