31. Executive Order No. 11375, ''Equal Employment Opportunity'' (Oct. 13, 1967, 32 FR 14303);

32. Executive Order No. 11988, ''Floodplain Management'' (May 24, 1977, 42 FR 26951);

33. Executive Order No. 11990, ''Protection of Wetlands'' (May 24, 1977, 42 FR 26961);

34. Executive Order No. 12072, ''Federal Space Management'' (Aug. 16, 1978, 43 FR 36869);

35. Executive Order No. 12699, ''Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction'' (Jan. 5, 1990, 55 FR 835);

36. Executive Order No. 13006, ''Locating Federal Facilities on Historic Properties in Our Nation's Central Cities'' (May 1, 1996, 61 FR 26071);

37. Executive Order No. 13423, ''Strengthening Federal Environmental, Energy and Transportation Management'' (January 26, 2007, 72 FR 3919);

38. Executive Order No. 13327, ''Federal Real Property Asset Management'' (Feb. 4, 2004, 69 FR 5897);

39. Executive Order No. 13514, ''Federal Leadership in Environmental, Energy, and Economic Performance'' (Oct. 5, 2009, 74 FR 52117);

40. Executive Order No. 13576, ''Delivering Efficient, Effective, and Accountable Government'' (Jun. 13, 2011, 76 FR 35297);

41. Executive Order No. 12941, ''Seismic Safety of Existing Federally Owned or Leased Buildings'' (Dec. 5, 1994, 59 FR 62545);

42. Comprehensive Procurement Guideline For Products Containing Recovered Materials (40 CFR chapter I, part 247);

43. OMB Circular A–11 (Capital Lease Scoring);

44. OMB Memorandum M–12–12, ''Promoting Efficient Spending to Support Agency Operations'' (May 11, 2012), and OMB Management Procedures Memorandum No. 2013–02, ''Implementation of OMB Memorandum M–12–12 Section 3: Freeze the Footprint'' (March 14, 2013);

45. Federal Management Regulation (41 CFR chapter 102);

46. General Services Administration Acquisition Manual, including the General Services Administration Acquisition Regulation (48 CFR chapter 5); and

47. The General Services Administration, Public Buildings Service, Leasing Desk Guide.

By delegation of the Administrator of General Services.

Anne E. Rung,

Associate Administrator.

[FR Doc. 2014–08645 Filed 4–15–14; 8:45 am]

BILLING CODE 6820–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0258]

Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission

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 of FDA's regulations for submission of petitions, including food and color additive petitions (including labeling) and Generally Recognized as Safe (GRAS) affirmations, submission of information to a master file in support of petitions, and electronic submission using FDA Form 3503.

DATES: Submit either electronic or written comments on the collection of information by June 16, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using FDA Form 3503—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179 and 180 (OMB Control Number 0910–0016)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or intended use, are in conformity with a regulation issued under section 409 of the FD&C Act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the FD&C Act is effective.

Food additive petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the FD&C Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the FD&C Act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the Agency's regulations specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review CAPs to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Under section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures or common use in food. The FD&C Act historically has been interpreted to permit food manufacturers to make their own initial determination that use of a substance in food is GRAS and thereafter seek affirmation of GRAS status from FDA. FDA reviews petitions for affirmation of GRAS status that are submitted on a voluntary basis by the food industry and other interested parties under authority of sections 201, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 342, 348, and 371). To implement the GRAS provisions of the FD&C Act, FDA has set forth procedures for the GRAS affirmation petition process in 21 CFR 170.35(c)(1) of its regulations. While the GRAS affirmation petition process still exists, FDA has not received a GRAS affirmation petition since the establishment of the voluntary GRAS notification program and is not expecting any during the period covered by this proposed extension of collection of information.

Interested persons may transmit FAP or CAP regulatory submissions in electronic format or paper format to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503. Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review. Form FDA 3503 can also be used to organize information within a master file submitted in support of Petitions according to the items listed on the form. Master files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food and color additive approvals. FDA estimates that the amount of time for respondents to complete FDA Form 3503 will continue to be 1 hour.

Description of respondents: Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section/FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
CAPs						
70.25, 71.1	2	1	2	1,337	2,674	$5,600
GRAS Affirmation Petitions						
170.35	1 or fewer	1	1 or fewer	2,614	2,614	0
FAPs						
171.1	3	1	3	7,093	21,279	0
FDA Form 3503	6	1	6	1	6	0
Total					26,573	$5,600

The estimate of burden for food additive, color additive, or GRAS affirmation petitions is based on FDA's experience with the petition process. FDA is retaining its prior estimate of the number of petitions received because the average number of petitions received annually has varied little over the past 10 years. The figures for hours per response are based on estimates from experienced persons in the Agency and in industry. Although the estimated hour burden varies with the type of petition submitted, an average petition involves analytical work and appropriate toxicological studies, as well as the work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color

additive petition ranges from $1,600 to $3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in § 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is $2,600 and the maximum color additive petition fee for a Category B petition is $3,000. Because an average of 2 color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this start-up cost would be less than or equal to $5,600 (1 × $2,600 + 1 × $3,000 listing fees = $5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the FD&C Act and other specific labeling acts administered by FDA. Label information does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: April 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08590 Filed 4–15–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs Products: Common European Medicines Agency/Food and Drug Administration Application Form for Orphan Medicinal Product Designation

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 Orphan Drug Products: Common EMEA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671).

DATES: Submit written or electronic comments on the collection of information by June 16, 2014.

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.

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Orphan Drugs—21 CFR Part 316 (OMB Control Number 0910–0167)—Extension

FDA is amending the 1992 Orphan Drug Regulations, part 316 (21 CFR part 316). The 1992 regulations were issued to implement sections 525 through 528 of the Orphan Drug Act Amendments to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360aa through 360ee) (the FD&C Act). The 1992 regulations specify the procedures for sponsors of orphan drugs to use in obtaining the incentives provided for in the FD&C Act and set forth the procedures that FDA will use in administering the FD&C Act.

The amendments are intended to clarify regulatory provisions and make minor improvements to address issues that have arisen since the issuance of the regulations in 1992. They are intended to assist sponsors who are seeking and who have obtained orphan drug designations, as well as FDA in its administration of the orphan drug program. Except with respect to the two revisions addressed further, the revisions in this rule clarify existing language and do not constitute a substantive or material modification to the approved collections of information in current part 316 (see 5 CFR 1320.5(g)). The collections of information in current part 316 have been approved by OMB in accordance with the PRA under OMB control number 0910–0167.