comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agencies, including whether the information shall have practical utility; (b) the accuracy of the agencies' estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer, Administration for Children and Families.

[FR Doc. 2012–812 Filed 1–17–12; 8:45 am]

BILLING CODE 4184–09–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care and Development Fund Annual Aggregate Report—ACF–800.

OMB No.: 0970–0150.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101–508, 42 U.S.C. 9858) requires that States and Territories submit annual aggregate data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Annual aggregate reports include data elements represented in the ACF–800 reflecting the scope, type, and methods of child care delivery. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF–800.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–800	56	1	40	2,240

Estimated Total Annual Burden Hours: 2,240

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–737 Filed 1–17–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

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 the Notification Procedure for Substances Generally Recognized as Safe (GRAS) and new Form FDA 3667, which may be submitted electronically via the Electronic Submission Gateway (ESG).

DATES: Submit either electronic or written comments on the collection of information by March 19, 2012.

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: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

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.

Substances Generally Recognized as Safe: Notification Procedure—21 CFR 170.36 and 570.36 (OMB Control Number 0910–0342)—Revision

I. Background

Section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the FD&C Act (21 U.S.C. 321) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. In the **Federal Register** of April 17, 1997 (62 FR 18938) (the 1997 proposed rule), FDA published a proposed rule that would establish a voluntary procedure whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket approval requirements based on a determination that such use is GRAS. The proposed regulations (proposed 21 CFR 170.36 and 21 CFR 570.36) provide a standard format for the voluntary submission of a notice. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the subject of the GRAS notice, and the Agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes. In the **Federal Register** of December 28, 2010 (75 FR 81536) (the GRAS reopener), FDA announced the reopening of the comment period for the 1997 proposed rule. The Agency requested that comments be submitted by March 28, 2011.

FDA's Center for Food Safety and Applied Nutrition (CFSAN) has recently developed a form that prompts a notifier to include certain elements of a GRAS notice in a standard format. New Form FDA 3667 is entitled ''Generally Recognized as Safe (GRAS) Notice.'' The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the ESG, or may be submitted in paper format, or as electronic files on physical media with paper signature page. CFSAN expects that most if not all businesses filing GRAS notices in the next 3 years will choose to take advantage of the option of electronically submitting their GRAS notice. Thus, the burden estimate in table 1, line 1 is based on the expectation of 100 percent participation in the electronic submission process.

FDA's Center for Veterinary Medicine (CVM) continues to comply with the GRAS Pilot Program procedures announced on June 4, 2010 (75 FR 31800).

II. GRAS Information on Form FDA 3667

The GRAS notice submitted to CFSAN includes the following information on Form FDA 3667 and in attachments to the form:

A. Introductory Information About the Submission

- Whether the GRAS notice submission is a new GRAS notice, or an amendment or supplement to a previously transmitted GRAS notice;
- Whether the notifier has determined that all files provided in an electronic transmission are free of computer viruses;
- The date of the notifier's most recent meeting with FDA before transmitting a new GRAS notice; and
- The date of any correspondence, sent to the notifier by FDA, relevant to an amendment or supplement the notifier is transmitting.

B. Information About the Notifier

- The name of and contact information for the notifier, including the identity of the contact person and the company name (if applicable); and
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the notifier.

C. General Administrative Information

- The name of the substance that is the subject of the GRAS notice submission;
- The format of the submission (*i.e.,* paper, electronic, or electronic with a paper signature page);
- The mode of transmission of any electronic submission (*i.e.,* ESG or transmission on physical media such as CD–ROM or DVD);
- Whether the notifier is referring us to information already in our files;
- The statutory basis for the notifier's determination of GRAS status;
- Whether the notifier has designated in its submission any information as trade secret or as confidential commercial or financial information; and
- Whether the notifier has attached a redacted copy of some or all of the submission.

D. Intended Use

- The intended conditions of use of the notified substance.

E. Identity

- Information that identifies the notified substance. For example, there may be a chemical name and formula and a standardized registry number.

F. Checklist of Other Elements Not Completed Directly on Form FDA 3667

- Any additional information about identity not previously covered;
- Method of manufacture;
- Specifications for food-grade material;

- Dietary exposure;
- Self-limiting levels of use;
- Common use in food before 1958 (if applicable);
- Comprehensive discussion of the basis for the determination of GRAS status; and
- Bibliography.

Form FDA 3667 also requires the signature of a responsible official (or agent or attorney) and a list of attachments.

The information is used by FDA to evaluate whether the notice provides a sufficient basis for a conclusion of GRAS status and whether information in the notice or otherwise available to FDA raises issues of public health significance that lead the Agency to question whether use of the substance is GRAS.

III. Description of Respondents

The respondents to this collection of information are manufacturers of substances used in food and feed.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA Form No.[2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.36 (CFSAN)	FDA 3667 [3]	40	1	40	150	6,000
570.36 (CVM)	N/A	20	1	20	150	3,000
Total						9,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Only CFSAN uses Form FDA 3667. CVM continues to comply with the GRAS Pilot Program procedures announced on June 4, 2010 (75 FR 31800).
[3] Form FDA 3667 may be submitted electronically via the ESG.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
170.36(c)(v) (CFSAN)	40	1	40	15	600
570.36(c)(v) (CVM)	20	1	20	15	300
Total					900

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

As noted, CFSAN estimates that all of the future Form FDA 3667 submissions will be made electronically via the ESG. 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–$30.

Both CFSAN and CVM receive submissions that are intended by the submitter to be GRAS notices. Not all of the submissions received contain sufficient information to be filed by the Agency as GRAS notices. In the December 28, 2010, GRAS reopener, FDA requested comment on its GRAS submission filing decision process and described its current preliminary review process of GRAS submissions (75 FR 81536, at 81543). Therefore, the Agency is basing the following estimates on the number of GRAS notices that have been filed by the relevant Center.

In the 1997 proposed rule, FDA estimated that CFSAN would file approximately 50 GRAS notices per year and that CVM would file approximately 10 GRAS notices per year. Approval for the GRAS notification program was granted by OMB on June 16, 1997, under OMB control number 0910–0342. In 2009, FDA's estimate of the annual number of GRAS notices that will be filed by CFSAN and CVM was revised downward from the original PRA approval, based on the actual number of GRAS notices filed by CFSAN from 1998 to 2008. In 2009, FDA sought and OMB approved an estimate that CFSAN would file 25 GRAS notices and CVM would file 5 GRAS notices. On June 4, 2010 CVM announced the beginning of a GRAS Pilot Program (75 FR 31800). This notice stated that the revised estimate in the 2009 PRA approval reflected FDA's best judgment at the time as to the number of notices CVM will file annually through this pilot program.

For purposes of this extension request, CFSAN and CVM are re-evaluating their estimates of the annual number of GRAS notices that will be received by CFSAN and CVM in the next 3 years, 2012 through 2015. CFSAN filed 365 GRAS notices during the 13-year period from 1998 through 2010, for an average of approximately 28 GRAS notices per year. However, recent years have seen an increase in the number of GRAS notices filed, with 36 notices filed in both 2008 and 2009 and 55 notices in 2010. Based on an approximate average from the last 3 years, FDA is revising its estimate of the annual number of GRAS notices filed by CFSAN to be 40 or less. CFSAN expects that most if not all businesses filing GRAS notices in the next 3 years will choose to take advantage of the option of electronically submitting their GRAS notice. We expect participation to be 100 percent; thus the estimate in Table 1 is based on the burden of that experience. FDA also is revising its estimate of the annual number of GRAS notices submitted to CVM. As noted, on June 4, 2010, CVM announced the beginning of a GRAS Pilot Program. From June 2010 to October 2011, CVM filed 13 GRAS notices. Based on this experience, FDA is revising its estimate of the annual number of GRAS notices filed by CVM to be 20 or less.

In the 1997 proposed rule, FDA estimated that the notification procedures would require 150 hours per response for the reporting burdens and 15 hours per response for the recordkeeping burdens for both proposed sections (§§ 170.36 and 570.36). FDA is retaining these

estimates for this request. The availability of the form, and the opportunity to provide the information in electronic format, could reduce this estimate. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the form and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a GRAS notification.

Dated: January 11, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–783 Filed 1–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–P–0756]

Determination That PREZISTA (darunavir) Tablets, 300 Milligrams Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PREZISTA (darunavir) Tablets, 300 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for darunavir tablets, 300 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nam Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6320, Silver Spring, MD 20993–0002, (301) 796–3472.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PREZISTA (darunavir) Tablets, 300 mg, is the subject of NDA 21–976, held by Tibotec, Inc., and initially approved on June 23, 2006. PREZISTA is a human immunodeficiency virus (HIV–1) protease inhibitor indicated for the treatment of HIV–1 infection in adult patients. PREZISTA is also indicated for the treatment of HIV–1 infection in pediatric patients 6 years of age and older. PREZISTA must be coadministered with ritonavir (PREZISTA/ritonavir) and with other antiretroviral agents.

PREZISTA (darunavir) Tablets, 300 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Lupin Pharmaceuticals, Inc. (Lupin), submitted a citizen petition dated October 14, 2011 (Docket No. FDA–2011–P–0756), under 21 CFR 10.30, requesting that the Agency determine whether PREZISTA (darunavir) Tablets, 300 mg, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PREZISTA (darunavir) Tablets, 300 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner Lupin has identified no data or other information suggesting that PREZISTA (darunavir) Tablets, 300 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PREZISTA (darunavir) Tablets, 300 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PREZISTA (darunavir) Tablets, 300 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PREZISTA (darunavir) Tablets, 300 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: *January 11, 2012.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–847 Filed 1–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0020 (formerly Docket No. 2007D–0249)]

Guidance for Industry: Preparation of Investigational Device Exemptions and Investigational New Drug Applications for Products Intended To Repair or Replace Knee Cartilage; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage'' dated December 2011. The guidance document provides sponsors of an investigational device exemption application (IDE) or an investigational new drug application (IND) recommendations about certain information that should be included in