ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Preparation and Submission of Data Verification Procedures §§ 261.60–261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202 §§ 261.41 & 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process §§ 262.4, 262.6, & 262.7; § 261.51	54	2	240	25,920
TANF Data Report Part 265	54	4	2,201	475,416
SSP–MOE Data Report Part 265	29	4	714	82,824
Estimated Total Annual Burden Hours				625,200

Additional Information:

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–12498 Filed 5–29–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0575]

Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics.'' The purpose of this guidance is to provide a single resource for information on FDA's policies and procedures related to expedited drug development and review programs. The following programs are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition (expedited programs): Fast track designation, breakthrough therapy designation, accelerated approval, and priority review designation. This guidance finalizes the draft guidance issued in June 2013.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.

Submit electronic comments on the guidance 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: Melissa Robb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–2500; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics.'' This guidance provides a single resource for information on FDA's policies and procedures related to the following expedited programs for serious conditions: (1) Fast track designation, (2) breakthrough therapy designation, (3) accelerated approval, and (4) priority review designation. The guidance describes threshold criteria generally applicable to expedited programs, including what is meant by serious condition, unmet medical need, and available therapy. This guidance also discusses considerations for expedited development and review such as manufacturing and product quality, nonclinical studies, and clinical inspections. In addition, this guidance aligns CDER's criteria for priority review designation with CBER's criteria. Only products intended to treat a serious condition are eligible for priority review (unless otherwise eligible under specific statutory provisions).

For over 30 years, expediting the availability of promising therapies to patients with serious conditions has been a priority for FDA. With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112–122), FDA is expanding its efforts to expedite development and review of therapies intended to treat patients with serious conditions. This guidance is intended to satisfy the statutory requirements of sections 901(c)(2) and 902(b)(1)(A) of FDASIA.

Section 901(c)(2) of FDASIA requires FDA to issue a final guidance document to implement amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) made by section 901 of

FDASIA (Enhancement of Accelerated Approval Access to New Medical Treatments) within 1 year of the date the draft guidance issues. The discussions of accelerated approval, and other more broadly applicable provisions in this guidance, are intended to meet this requirement.

Section 902(b)(1)(A) of FDASIA requires FDA to issue a guidance document to implement requirements of section 902 (Breakthrough Therapies) within 1 year of the date the comment period closes for the draft guidance. The breakthrough therapy discussion and other more broadly applicable provisions in this guidance are intended to meet this requirement.

In the **Federal Register** of June 26, 2013 (78 FR 38349), FDA announced the availability of the draft guidance entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics.'' The notice gave the public an opportunity to comment by August 26, 2013. FDA carefully considered all comments received in developing the final guidance. This guidance addresses the applicability of expedited programs to rare diseases, clarification on available therapy, and additional detail on possible flexibility in manufacturing and product quality. The guidance also includes clarification on the qualifying criteria for breakthrough therapy designation and examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval. This guidance finalizes the draft guidance issued in June 2013.

The provisions of this guidance relating to fast track development and other issues such as serious condition and unmet medical need, replace the guidance for industry entitled ''Fast Track Drug Development Programs—Designation, Development, and Application Review.'' The provisions of this guidance pertaining to available therapy replace the guidance for industry entitled ''Available Therapy.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on expedited programs for serious conditions—drugs and biologics. It does not create or confer any rights for or on any person and does 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.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 202.1, certain parts of 21 CFR part 314, 21 CFR part 601, and sections 506(b)(1), 735, and 736 of the FD&C Act (21 U.S.C. 356(b)(1), 379g, and 379h) have been approved under OMB control numbers 0910–0686, 0910–0001, 0910–0338, 0910–0389, 0910–0297, and 0910–0765.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

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

Dated: May 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12534 Filed 5–29–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–1227]

Determination of Regulatory Review Period for Purposes of Patent Extension; KALYDECO

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for KALYDECO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product KALYDECO (ivacaftor). KALYDECO is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the CFTR gene.