and associated materials (see **ADDRESSES**).

CMS–10453 The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits and Supporting Regulations

CMS–1856 Request for Certification in the Medicare/Medicaid Program for Providers of Outpatient Physical Therapy and/or Speech-Language Pathology

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

**Information Collection**

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* The Medicare Advantage and Prescription Drug Program: Part C Explanation of Benefits and Supporting Regulations; *Use:* The Medicare Advantage disclosure requirements in 42 CFR 422.111(b) sets out the authority for CMS to require that Medicare Advantage Organizations (MAOs) furnish a written explanation of benefits (EOB) directly to enrollees, in a manner specified by CMS and in a form easily understandable to enrollees, when benefits are provided under part 422. In § 422.216(d)(1), all Medicare Advantage plan types that offer an M+C fee-for-service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee's liability for deductibles, coinsurance, copayment, and balance billing. Plans must disclose the information specified in § 422.111(b), as specified in § 422.111(a)(3), at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period. *Form Number:* CMS–10453 (OMB control number: 0938–1228); *Frequency:* On occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 468; *Number of Responses:* 5,616; *Total Annual Hours:* 74,880. (For policy questions regarding this collection contact Natalie Albright at 410–786–1671.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Request for Certification in the Medicare/Medicaid Program for Providers of Outpatient Physical Therapy and/or Speech-Language Pathology; *Use:* The form is used as an application to be completed by providers of outpatient physical therapy and/or speech-language pathology services requesting participation in the Medicare and Medicaid programs. This form initiates the process for obtaining a decision as to whether the conditions of participation are met as a provider of outpatient physical therapy, speech-language pathology services, or both. It is used by the State agencies to enter new providers into the Automated Survey Process Environment (ASPEN). *Form Number:* CMS–1856 (OMB control number: 0938–0065); *Frequency:* Annually, occasionally; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 350; *Total Annual Responses*: 350; *Total Annual Hours:* 88. (For policy questions regarding this collection contact Peter Ajuonuma at 410–786–3580.)

Dated: February 2, 2018.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2018–02433 Filed 2–6–18; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–D–0575]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Expedited Programs for Serious Conditions—Drugs and Biologics

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by March 9, 2018.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0389. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Guidance for Industry**: ''**Expedited Programs for Serious Conditions—Drugs and Biologics**''

**OMB Control Numbers 0910–0389 and 0910–0765—Revision**

This information collection supports the previous captioned Agency guidance. The 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. The 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 clarifies the qualifying criteria for breakthrough therapy designation and provides examples of surrogate endpoints and intermediate clinical endpoints used to support accelerated approval.

In the **Federal Register** of November 8, 2017 (82 FR 51846), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received. We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Guidance for industry: Expedited programs for serious conditions—Drugs and biologics | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Priority review designation request (0765) | 48 | 1.7 | 82 | 30 | 2,400 |
| Breakthrough therapy designation request (0765) | 87 | 1.29 | 113 | 70 | 7,910 |
| Fast track designation request (0389) | 140 | 1.33 | 187 | 60 | 11,220 |
| Fast track premeeting packages (0389) | 107 | 1.23 | 132 | 100 | 13,200 |
| Total | | | | | 34,730 |

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

The information collection elements regarding priority review designation and breakthrough therapy designation requests are reflected in rows 1 and 2 of table 1 and are currently approved under OMB control number 0910–0765. Meanwhile, fast track designation requests and premeeting packages are currently approved under OMB Control No. 0910–0389. We are therefore revising OMB control number 0910–0389 to include all four collection elements. Information collection burden for accelerated approval requests is currently approved under OMB control numbers 0910–0001 (drugs) and 0910–0338 (biologics). The estimates provided are based on our experience with the respective collection elements over the past 3 years.

A sponsor or applicant who seeks fast track designation is required to submit a request to the Agency showing that the drug product: (1) Is intended for a serious or life-threatening condition, and (2) has the potential to address an unmet medical need. The Agency expects that most information to support a designation request will have been gathered under existing requirements for preparing an investigational new drug (IND), new drug application (NDA), or biologics license application (BLA). If such information has already been submitted to the Agency, the information may be summarized in the fast track designation request. A designation request should include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the Agency expects that most sponsors or applicants will have gathered such information to meet existing requirements for preparing an IND, NDA, or BLA. These may include descriptions of clinical safety and efficacy trials not conducted under an IND (*e.g.,* foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package.

The Agency estimates the total annual number of respondents submitting requests for fast track designation is approximately 140, and the number of requests received is approximately 187 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request (row 3 in table 1).

Of the requests for fast track designation made per year, the Agency granted approximately 132 requests from 107 respondents, and for each of these granted requests, a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package (row 4 in table 1). The total burden hours for fast track designation and fast track meetings has increased due to increased requests; however, the hours per request have remained the same.

Dated: February 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–02415 Filed 2–6–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–E–1240]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; SEDASYS SYSTEM

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined the regulatory review period for SEDASYS SYSTEM 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 the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 9, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 6, 2018. See ''Petitions'' in the