electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device OPTIMIZER. OPTIMIZER is indicated to improve 6-minute hall walk distance, quality of life, and functional status of New York Heart Association Class III heart failure patients who remain symptomatic despite guideline-directed medical therapy, are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25 percent to 45 percent. Subsequent to this approval, the USPTO received a patent term restoration application for OPTIMIZER (U.S. Patent Nos. 8,260,416 and 8,311,629) from Impulse Dynamics N.V., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 9, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of OPTIMIZER represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for OPTIMIZER is 5,434 days. Of this time, 5,236 days occurred during the testing phase of the regulatory review period, while 198 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* May 6, 2004. FDA has verified the applicant's claim that the date the investigational device exemption for human tests to begin, as required under section 520(g) of the FD&C Act, became effective May 6, 2004.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* September 5, 2018. FDA has verified the applicant's claim that the premarket approval application (PMA) for OPTIMIZER (PMA 180036) was initially submitted September 5, 2018.

3. *The date the application was approved:* March 21, 2019. FDA has verified the applicant's claim that PMA 180036 was approved on March 21, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,258 days or 1,293 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

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

Dated: June 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12192 Filed 6–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0115]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Principle

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by July 12, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0594. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *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 and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle

OMB Control Number 0910–0594—Extension

This information collection supports Agency regulations. Under the Safe Medical Devices Act of 1990 (Pub. L. 101–629), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The special control guidance serves as the special control for the automated blood cell separator device operating by centrifugal or filtration separation principle intended for the routine collection of blood and blood components (§ 864.9245 (21 CFR 864.9245)). The guidance entitled ''Guidance for Industry and FDA Staff—Class II Special Controls Guidance Document: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle'' is available at *https://www.fda.gov/media/124263/download.*

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Reclassification of this device from class III to class II relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e) and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under 21 CFR part 814, subpart E, including the submission of periodic reports under 21 CFR 814.84.

Collecting or transfusing facilities, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the device manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b) (21 CFR 803.50(b)). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected.

In the **Federal Register** of February 18, 2021 (86 FR 10108), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report	3	1	3	5	15

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

Based on FDA records, there are approximately three manufactures of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report. Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimates.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 3, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12191 Filed 6–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0315]

Electronic Study Data Submission; Data Standards; Support and Requirement Begin for Study Data Tabulation Model Version 1.8 With Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule Version 1.0; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** on March 11, 2020. The document announced that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule version 1.0 (SENDIG–AR v1.0) on March 15, 2020, and that these new standards will be required in submissions to FDA effective March 15, 2022. The document omitted the 36-month implementation period for certain investigational new drugs applications (INDs) as required by the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' which is referenced in that document. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chenoa Conley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, 301–796–0035, email: *cderdatastandards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 11, 2020 (85 FR 14205), in FR Doc. 2020–04898, the following corrections are made:

1. On page 14205, in the second column, the first sentence of the **SUMMARY** is corrected to read: ''The Food and Drug Administration (FDA or Agency) Center for Drug Evaluation and Research (CDER) is announcing that FDA will begin supporting the Clinical Data Interchange Standards Consortium (CDISC) for Study Data Tabulation Model version 1.8 (SDTM v1.8), and CDISC Standard for Exchange of Nonclinical Data Implementation Guide—Animal Rule version 1.0 (SENDIG–AR v1.0) on March 15, 2020, and that these new standards will be required in submissions for studies that start after March 15, 2022 (for new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics license applications (BLAs)), and in submissions for studies that start after March 15, 2023 (for certain investigational new drug applications (INDs)), that are submitted to CDER.''

2. On page 14206, in the first column, the last sentence of the document is corrected to read as follows: ''FDA will begin supporting SDTM v1.8 and SENDIG–AR v1.0 on March 15, 2020, and the use of these new standards will be required in Animal Rule [1] submissions for studies that start after March 15, 2022 (for NDAs, ANDAs, and BLAs), and in Animal Rule submissions for studies that start after March 15, 2023 (for certain INDs), that are submitted to CDER.''

Dated: June 4, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–12198 Filed 6–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0362]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by July 12, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0139. 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.

Current Good Manufacturing Practice for Finished Pharmaceuticals, Including Medical Gases, and Active Pharmaceutical Ingredients—21 CFR Parts 210 and 211 and 21 U.S.C 351(a)(2)(B)

OMB Control Number 0910–0139—Extension

This information collection supports FDA regulations that govern the manufacture, processing, packing, or holding of finished pharmaceuticals, including medical gases, and active pharmaceutical ingredients (APIs). Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (CGMP) regulations. FDA is responsible for enforcing the FD&C Act as well as related statutes, including the Public Health Service Act. Congress enacted these laws to ensure that covered products meet applicable requirements regarding the safety, identity and strength, and the quality

[1] The Animal Rule refers to FDA's regulations for the approval of new drugs and biological products when human efficacy studies are not ethical or feasible (see 21 CFR 314.600–650 for drugs and 21 CFR 601.90–95 for biologics).