a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies, total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments, and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the 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.

FOR FURTHER INFORMATION CONTACT: Gretchen Opper, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations (21 CFR 814.44(d) and 814.45(d)) provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of PMAs approved by CBER for which safety and effectiveness summaries were placed on the internet from October 1, 2017, through December 31, 2018. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM OCTOBER 1, 2017, THROUGH DECEMBER 31, 2018

PMA No./Docket No.	Applicant	Trade name	Approval date
BP160122, FDA–2017–M–6870.	Ortho-Clinical Diagnostics, Inc	VITROS Immunodiagnostic Products HIV Combo Reagent Pack & VITROS Immunodiagnostic Products HIV Combo Calibrator.	December 13, 2017.
BP170122, FDA–2018–M–3584.	Avita Medical Americas, LLC	RECELL Autologous Cell Harvesting Device.	September 20, 2018.
BP170154, FDA–2018–M–3870.	Progenika Biopharma, S.A	ID CORE XT (Reagents and Analysis Software).	October 11, 2018.

II. Electronic Access

Persons with access to the internet may obtain the documents at *https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/default.htm.*

Dated: March 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04114 Filed 3–6–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for an opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Before submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than May 6, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft

instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310, Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114–104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database, which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. Over time, there is an expected increase in the number of recipients for whom data are reported as the increasing number of transplants are performed annually and survivorship after transplantation improves.

Need and Proposed Use of the Information: Per statutory responsibilities, information collected on the forms outlined in the ''Total Estimated Annualized Burden Hours'' section below is needed to monitor the clinical status of transplantation and provide the Secretary with an annual report of transplant center-specific survival data. The proposed revisions of these data collection forms fall into several categories: Consolidating questions and removing duplicate questions across the forms, implementing ''check all that apply'' formatting to reduce data entry time, and removing items no longer clinically significant (*e.g.,* drugs). These proposed revisions are not anticipated to affect total burden hours.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents [1]	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Baseline Pre-Transplant Essential Data (TED)	200	44	8,800	1.00	8,800
Disease Classification	200	44	8,800	0.15	1,320
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	33	6,600	1.00	6,600
100-Day Post-TED	200	44	8,800	1.25	11,000
6-Month Post-TED	200	36	7,200	1.15	8,280
12-Month Post-TED	200	32	6,400	1.15	7,360
Annual Post-TED	200	110	22,000	1.15	25,300
Total	200		68,600		68,660

[1] The total of 200 is the number of centers completing the form; the same group will complete all of the forms.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–04117 Filed 3–6–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Nurse Education and Practice

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the National Advisory Council on Nurse Education and Practice (NACNEP) has scheduled public meetings for the 2019 calendar year (CY). Information about NACNEP, agendas, and materials for these meetings can be found on the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing/index.html.*

DATES: All CY 2019 NACNEP meetings will be held by teleconference and webinar:

- April 1, 2019, 8:30 a.m.–2:30 p.m. Eastern Time (ET)
- May 21, 2019, 8:30 a.m.–5:00 p.m. ET; and
- September 24, 2019, 8:30 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings will be held by teleconference and/or Adobe Connect webinar. Instructions for joining the meetings remotely will be posted on the