INCLUSION AND EXCLUSION CRITERIA BY POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING/STUDY DESIGN (PICOTS)—Continued

Element	*Inclusion criteria*	*Exclusion criteria*
Outcome	*KQ1:* *Newborn size and body composition.* • Birth weight, weight-for-age and percentile or Z-score adjusted for gestational age. • Low birth weight. • Small-for-gestational age. • Large-for-gestational age; fetal macrosomia. • Birth length, length-for-age and percentile and Z-score adjusted for gestational age. • Head circumference and percentile and Z-score adjusted for gestational age. • BMI, BMI z-score, weight-for-length percentile, and Z-score • Ponderal index or other composite measures. • Body composition and distribution (*e.g.,* % fat mass, fat-free mass, skin fold thicknesses, circumferences). *KQ2:* *Gestational weight gain.* • Change in pregnant individual's body weight from baseline (before or during 1st trimester of pregnancy) to a later time point during pregnancy and/or right before delivery. • Weight gain in relationship to weight gain recommendations, based on pre-pregnancy BMI. *KQ3:* *Infant (up to 24 months of age) growth, size, and body composition.* • Weight-for-age and percentile or Z-score adjusted for gestational age. • Length-for-age and percentile and Z-score adjusted for gestational age. • Head circumference and percentile and Z-score adjusted for gestational age. • BMI, BMI z-score, weight-for-length percentile, and Z-score • Body composition and distribution (*e.g.,* % fat mass, fat-free mass, skin fold thicknesses, circumferences). • Incidence and prevalence of underweight, failure to thrive, stunting, wasting, healthy weight, overweight, obesity.	
Timing	• All exposure or intervention durations will be included. • KQ1 and KQ2: exposure during pregnancy. • KQ3: exposure from birth to 24 months of age.	
Setting	• Outpatient; all settings except hospital and acute care will be included.	• Hospital and acute care.
Study Design	• Randomized controlled trials. • Non-randomized controlled trials, including quasi-experimental and controlled before-and-after studies. • Prospective cohort studies. • Nested case-control studies.	• Narrative reviews. • Systematic reviews. • Meta-analyses. • Scoping reviews. • Umbrella reviews. • Retrospective cohort studies. • Cross-sectional studies. • Case-control studies. • All other study designs.
Geographic Location	• Locations with food products or dietary supplements widely available to U.S. and/or Canadian consumers, including those rated high and very high on the Human Development Index (HDI)[c].	• Locations not rated high or very high on the HDI.
Study Size	• Studies with N ≥30 participants (for randomized clinical trials [RCTs]): ≥10 participants analyzed *per study arm*).	• Studies with N <30 participants (for RCTs: <10 participants analyzed *per study arm*), and without power calculation.
Language	• Articles published in English	• Articles published in languages other than English.
Publication Dates	• Articles published during or after 2000	• Articles published prior to 2000.

[a] Total dietary digestible carbohydrate intake defined as collective starch and sugar intake; carbohydrate intake not including dietary fiber.
[b] Dietary supplement is defined as a product intended to supplement the diet that contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) intended to be taken by mouth as a pill, capsule, table, or liquid, and that is labeled on the front panel as being a dietary supplement.
[c] United Nations Development Programme Human Development Reports, *https://hdr.undp.org/data-center/human-development-index#/indicies/HDI.*

Dated: May 16, 2024.

Mamatha Pancholi,

Deputy Director.

[FR Doc. 2024–11198 Filed 5–21–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Privacy Act of 1974; System of Records; Correction

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice; Correction.

SUMMARY: The Department of Health and Human Services (HHS) published a system of records notice in the **Federal Register** on May 16, 2024, for new system of records ''OCSS Research Platform'' maintained by HHS' Administration for Children and Families (ACF), Office of Child Support Services (OCSS). The notice contained

an incorrect system number, 09–80–0391; the correct number is 09–80–0390.

FOR FURTHER INFORMATION CONTACT: Beth Kramer, HHS Privacy Act Officer, FOIA/Privacy Act Division, 200 Independence Ave. SW—Suite 729H, Washington, DC 20201, or *beth.kramer@hhs.gov,* (202) 690–6941.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of May 16, 2024, in FR Doc 2024–10776, on page 42881 (third column), correct the system number to read:

SYSTEM NAME AND NUMBER:

OCSS Research Platform, 09–80–0390.

Dated: May 17, 2024.

Beth Kramer,

HHS Privacy Act Officer, FOIA-Privacy Act Division, Office of the Assistant Secretary for Public Affairs.

[FR Doc. 2024–11267 Filed 5–21–24; 8:45 am]

BILLING CODE 4184–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2019]

Agency Information Collection Activities; Proposed Collection; Comment Request; Class II Special Controls: 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, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 collection of information concerning class II special controls for an automated blood cell separator device operating by centrifugal or filtration separation principle.

DATES: Either electronic or written comments on the collection of information must be submitted by July 22, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 22, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2019 for ''Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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