

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Eligible Participants	Behavioral Assessment PWID	3,333	1	43/60
Eligible Participant	Behavioral Assessment HET	3,333	1	31/60
Peer Recruiters	Recruiter Debriefing	3,333	1	2/60

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0577]

Proposed Information Collection Activity; Evaluation of LifeSet

Correction

In notice document 2022–16791, appearing on pages 48033 through 48034 in the issue of Friday, August 5, 2022, make the following corrections:

1. On page 48034, in the table, on the third row, in the second cell, “LifeSet Team

Supervisors” should appear below “LifeSet Specialists”.

2. On the same page, in the same table, remove the fourth row including the text “LifeSet Team Supervisors”.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1593]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

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 September 12, 2022.

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 0910–0823. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, 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.

Medical Device Accessories

OMB Control Number 0910–0823—Extension

FDA’s guidance document entitled “Medical Device Accessories—Describing Accessories and Classification Pathways”¹ is intended to provide guidance to industry and FDA staff about the regulation of accessories to medical devices, to describe FDA’s policy concerning the classification of accessories, and to discuss the application of this policy to devices that are commonly used as accessories to other medical devices. In addition, the guidance explains what devices FDA generally considers an “accessory” and describes the processes under section 513(f)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(6)) to

¹ The guidance document is available on FDA’s website (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-accessories-describing-accessories-and-classification-pathways>).

allow requests for risk- and regulatory control-based classification of accessories.

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) changed how FDA regulates medical device accessories. Specifically, section 707 of FDARA added section 513(f)(6) to the statute and requires that FDA, upon request, classify existing and new accessories notwithstanding the classification of any other device with which such accessory is intended to be used. This means that the classification of an accessory may not be the same as its parent device, depending on the risks of the accessory when used as intended and the level of regulatory controls necessary for reasonable assurance of safety and effectiveness of the accessory. Until an accessory is distinctly classified, its existing classification will continue to apply. This provision does not preclude a manufacturer from submitting a De Novo request for an accessory.

Depending on an accessory’s regulatory history, there are different submission types, tracking mechanisms, and deadlines:

(1) Existing accessory types are those that have been identified in a classification regulation or granted marketing authorization as part of a 510(k), premarket approval application (PMA), or De Novo request (approved under OMB control numbers 0910–0120, 0910–0231, and 0910–0844, respectively). Manufacturers with marketing authorization for an existing accessory may request appropriate classification through a new stand-alone premarket submission (Existing Accessory Request). Upon request, FDA is required to meet with a manufacturer or importer to discuss the appropriate classification of an existing accessory prior to submitting a written request. Existing Accessory Requests will be initially tracked as “Q-submissions” (approved under OMB control number 0910–0756). FDA has a statutory deadline of 85 calendar days to respond to an Existing Accessory Request.

(2) New accessory types are those that have not been granted marketing authorization as part of a 510(k), PMA,