underestimation given that these actions should not be a burdensome process for the recordkeeper.

(Comment 3) The commenter opposed changing the default from ''opt-in'' to ''opt-out'' for patients to consent to their tissue being used for research. Although simple malformations, such as warts and tumors, may be useful to labs to fine-tune their tests, and although many (even most) patients might be willing to share this tissue, a significant minority of Americans hold beliefs about the human body that would prevent them from consenting, and all Americans likely assume that their tissue is destroyed (burned as medical waste) after procedures have been performed. The commenter believes that changing what happens without changing the public understanding of what happens is fundamentally dishonest. The commenter recognizes that obtaining consent is time-consuming, particularly when the patient does not speak English as a first language, or has other comprehension issues; however, the commenter believes no lab has a right to the tissue of an American citizen for its private, profit-making use.

(Response) The subject of the comment deals with sample acquisition, a step that happens in advance of the information communicated in this guidance. Therefore, patient ''opt-in'' versus ''opt-out'' is out of scope. This guidance describes the enforcement discretion policy FDA uses when sponsors choose to use de-identified samples for IVD medical device clinical trials.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping regarding leftover human specimens that are not individually identifiable that are used in certain IVD studies	700	1	700	4	2,800

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

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: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–17026 Filed 8–7–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0006]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2018.

ADDRESSES: Copies are available at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. You also may access the docket at *http://www.regulations.gov* for the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2018. Insert the docket number found in brackets in the heading of this document at *http://www.regulations.gov* into the ''Search'' box, clear filter under Document Type (left side of screen), and check ''Supporting and Related Material,'' then Sort By Best Match (from the drop-down menu; top right side of screen), ''ID Number (Z–A)'' or Sort By Best Match (from the drop-down menu) ''Title (A–Z),'' also found in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Russell Fortney, Director, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1068.

SUPPLEMENTARY INFORMATION: Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2017, through September 30, 2018:

Center for Biologics Evaluation and Research:

Blood Products Advisory Committee

Vaccine and Related Biological Products Advisory Committee

National Center for Toxicological Research:

Science Board to the National Center for Toxicological Research

Center for Drug Evaluation and Research:

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee

Office of Commissioner

Joint Meeting of the Pediatric Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee

Annual Reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday, at:

(1) The Library of Congress, Madison Building, Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE, Rm. 133, Washington, DC; 20540; and

(2) Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: August 5, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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