Elaine L. Baker, MPH, DLP,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 2016–21400 Filed 9–6–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0514]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requests for Clinical Laboratory Improvement Amendments Categorization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by October 7, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0607. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Requests for Clinical Laboratory Improvement Amendments of 1988 Categorization—42 CFR 493.17—OMB Control Number 0910–0607—Extension

A guidance document entitled ''Guidance for Administrative Procedures for CLIA Categorization'' was released on May 7, 2008. The document describes procedures FDA uses to assign the complexity category to a device. Typically, FDA assigns complexity categorizations to devices at the time of clearance or approval of the device. In this way, no additional burden is incurred by the manufacturer because the labeling (including operating instructions) is included in the premarket notification (510(k)) or premarket approval application (PMA). In some cases, however, a manufacturer may request Clinical Laboratory Improvement Amendments of 1998 (CLIA) categorization even if FDA is not simultaneously reviewing a 510(k) or PMA. One example is when a manufacturer requests that FDA assign CLIA categorization to a previously cleared device that has changed names since the original CLIA categorization. Another example is when a device is exempt from premarket review. In such cases, the guidance recommends that manufacturers provide FDA with a copy of the package insert for the device and a cover letter indicating why the manufacturer is requesting a categorization (*e.g.* name change, exempt from 510(k) review). The guidance recommends that in the correspondence to FDA the manufacturer should identify the product code and classification as well as reference to the original 510(k) when this is available.

In the **Federal Register** of April 27, 2016 (81 FR 24820), 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	Total operating and maintenance costs
Request for CLIA Categorization	60	15	900	1	900	$46,800

[1] There are no capital costs associated with this collection of information.

The number of respondents is approximately 60. On average, each respondent will request categorizations (independent of a 510(k) or PMA) 15 times per year. The cost, not including personnel, is estimated at $52 per hour ($52 \times 900$), totaling $46,800. This includes the cost of copying and mailing copies of package inserts and a cover letter, which includes a statement of the reason for the request and reference to the original 510(k) numbers, including regulation numbers and product codes. The burden hours are based on FDA familiarity with the types of documentation typically included in a sponsor's categorization requests, and costs for basic office supplies (*e.g.,* paper).

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21352 Filed 9–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0731]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP).

DATES: Submit either written or electronic comments on the collection of information by November 7, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2013–N–0731 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice—OMB Control Number 0910–0543—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign

countries into the States. As derivatives of the human body, all HCT/Ps pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356, eligibility determination for donors, and CGTP.

Establishment Registration and Listing; Form FDA 3356

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute an HCT/P described in § 1271.10(a), or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)(2)). Section 1271.21(a) requires an establishment to follow certain procedures for initial registration and listing of HCT/Ps, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information. Section 1271.21(b), in brief, requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates if a change as described in § 1271.25(c) has occurred. Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of the establishment changes. FDA requires the use of a registration and listing form, Form FDA 3356: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps), to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26). To further facilitate the ease and speed of submissions, electronic submission is accepted at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/TissueEstablishmentRegistration/default.htm.*

Form FDA 3356 is being revised as follows: (1) Adding import contact information including an email address and phone number; (2) deleting columns related to HCT/Ps subject to registration and listing under 21 CFR part 207 or 807; and (3) revising the instructions accordingly. The estimated burden is not affected by these changes.

Eligibility Determination for Donors

In brief, FDA requires certain HCT/P establishments described in § 1271.1(b) to determine donor eligibility based on donor screening and testing for relevant communicable disease agents and diseases except as provided under § 1271.90. The documented determination of a donor's eligibility is made by a responsible person as defined in § 1271.3(t) and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)), and testing (§ 1271.50(a)). Certain records must accompany an HCT/P once the donor-eligibility determination has been made (§ 1271.55(a)). This requirement applies both to an HCT/P from a donor who is determined to be eligible as well as to an HCT/P from a donor who is determined to be ineligible or where the donor-eligibility determination is not complete if there is a documented urgent medical need, as defined in § 1271.3(u) (§ 1271.60). Once the donor-eligibility determination has been made, the HCT/P must be accompanied by a summary of records used to make the donor eligibility determination (§ 1271.55(b)), and a statement whether, based on the results of the screening and testing of the donor, the donor is determined to be eligible or ineligible (§ 1271.55(a)(2)). Records used in determining the eligibility of a donor, *i.e.,* results and interpretations of testing for relevant communicable disease agents, the donor-eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person (defined in § 1271.3(t)) who made the donor-eligibility determination and the date of the determination, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the original record must be maintained and translated to English, and accompanied by a statement of authenticity by the translator (§ 1271.55(d)(2)). HCT/P establishments must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or, if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest (§ 1271.55(d)(4)).

When a product is shipped in quarantine, as defined in § 1271.3(q), before completion of screening and testing, the HCT/P must be accompanied by records identifying the donor stating that the donor-eligibility determination has not been completed and stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination, except in cases of urgent medical need, as defined in § 1271.3(u) (§ 1271.60(c)). When a HCT/P is used in cases of documented urgent medical need, the results of any completed donor screening and testing, and a list of any required screening and testing that has not yet been completed also must accompany the HCT/P (§ 1271.60(d)(2)). When a HCT/P is used in cases of urgent medical need or from a donor who has been determined to be ineligible (as permitted under § 1271.65), documentation by the HCT/P establishment is required showing that the recipient's physician received notification that the testing and screening were not complete (in cases of urgent medical need), and upon the completion of the donor-eligibility determination, of the results of the determination (§§ 1271.60(d)(3) and (d)(4), and 1271.65(b)(3)).

An HCT/P establishment is also required to establish and maintain procedures for all steps that are performed in determining eligibility (§ 1271.47(a)), including the use of a product from a donor of viable, leukocyte-rich cells or tissue testing reactive for cytomegalovirus (§ 1271.85(b)(2)). The HCT/P establishment must record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence (§ 1271.47(d)).

Current Good Tissue Practice (CGTP)

FDA requires HCT/P establishments to follow CGTP (§ 1271.1(b)). Section 1271.155(a) permits the submission of a request for FDA approval of an exemption from or an alternative to any requirement in subpart C or D of part 1271. Section 1271.290(c) requires establishments to affix a distinct identification code to each HCT/P that they manufacture that relates the HCT/P to the donor and to all records pertaining to the HCT/P. Whenever an establishment distributes an HCT/P to a consignee, § 1271.290(f) requires the establishment to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill these requirements. Non-reproductive HCT/P establishments described in § 1271.10 are required under § 1271.350(a)(1) and (a)(3) to investigate and report to FDA adverse reactions (defined in § 1271.3(y)) using Form FDA 3500A (§ 1271.350(a)(2)). Form FDA 3500A is approved under OMB control number 0910–0291. Section 1271.370(b) and (c) requires establishments to include specific information either on the HCT/P label or with the HCT/P.

The standard operating procedures (SOP) provisions under part 1271 include the following: (1) § 1271.160(b)(2) (receiving, investigation, evaluating, and documenting information relating to core CGTP requirements, including complaints, and for sharing information with consignees and other establishments); (2) § 1271.180(a) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) § 1271.190(d)(1) (facility cleaning and sanitization); (4) § 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (5) § 1271.200(c) (calibration of equipment); (6) § 1271.230(a) and (c) (validation of a process and review and evaluation of changes to a validated process); (7) § 1271.250(a) (controls for labeling HCT/Ps); (8) § 1271.265(e) (receipt, predistribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) § 1271.265(f) (suitable for return to inventory); (10) § 1271.270(b) (records management system); (11) § 1271.290(b)(1) (system of HCT/P tracking); and (12) § 1271.320(a) (review, evaluation, and documentation of complaints as defined in § 1271.3(aa)).

Section 1271.155(f) requires an establishment operating under the terms of an exemption or alternative to maintain documentation of FDA's grant of the exemption or approval and the date on which it began operating under the terms of the exemption or alternative. Section 1271.160(b)(3) requires the quality program of an establishment that performs any step in the manufacture of HCT/Ps to document corrective actions relating to core CGTP requirements. Section 1271.160(b)(6) requires documentation of HCT/P deviations. Section 1271.160(d) requires, in brief, documentation of validation of computer software if the establishment relies upon it to comply with core CGTP requirements. Section 1271.190(d)(2) requires documentation of all cleaning and sanitation activities performed to prevent contamination of HCT/Ps. Section 1271.195(d) requires documentation of environmental control and monitoring activities. Section 1271.200(e) requires documentation of all equipment maintenance, cleaning, sanitizing, calibration, and other activities. Section 1271.210(d) requires, in brief, documentation of the receipt, verification, and use of each supply or reagent. Section 1271.230(a) requires documentation of validation activities and results when the results of processing described in § 1271.220 cannot be fully verified by subsequent inspection and tests. Section 1271.230(c) requires that when changes to a validated process subject to § 1271.230(a) occur, documentation of the review and evaluation of the process and revalidation, if necessary, must occur. Section 1271.260(d) and (e) requires documentation of any corrective action taken when proper storage conditions are not met and documentation of the storage temperature for HCT/Ps. Section 1271.265(c)(1) requires documentation that all release criteria have been met before distribution of an HCT/P. Section 1271.265(c)(3) requires documentation of any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of occurrence. Section 1271.265(e) requires documentation of the activities in paragraphs (a) through (d) of this section, which must include identification of the HCT/P and the establishment that supplied the HCT/P, activities performed and the results of each activity, date(s) of activity, quantity of HCT/P subject to the activity, and disposition of the HCT/P. Section 1271.270(a) requires documentation of each step in manufacturing required in part 1271, subparts C and D. Section 1271.270(e) requires documentation of the name and address, and a list of responsibilities of any establishment that performs a manufacturing step for the establishment. Section 1271.290(d) and (e) require documentation of a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor and to enable tracking from the donor to the consignee or final disposition. Section 1271.320(b) requires an establishment to maintain a record of each complaint that it receives. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint and for determining whether the complaint is an isolated event or represents a trend.

Respondents to this information collection are establishments that recover, process, store, label, package, or distribute any HCT/P, or perform donor screening or testing. The estimates provided below are based on most recent available information from FDA's database system and trade organizations. The hours per response and hours per record are based on data provided by the Eastern Research Group, or FDA experience with similar recordkeeping or reporting requirements.

There are an estimated 2,218 HCT/P establishments (conventional tissue, eye tissue, peripheral blood stem cell, stem cell products from cord blood, reproductive tissue, and sperm banks), including 667 manufacturers of HCT/P products regulated under the Federal Food, Drug, and Cosmetic Act and section 351 of the PHS Act (42 U.S.C. 262), that have registered and listed with FDA. In addition, we estimate that 182 new establishments have registered with FDA (§§ 1271.10(b)(1) and (b)(2) and 1271.25(a) and (b)). There are an estimated 1,221 listing updates (§§ 1271.10(b)(2), 1271.21(c)(ii), and 1271.25(c)) and 588 location/ownership amendments (§ 1271.26).

Under § 1271.55(a), an estimated total of 2,206,890 HCT/Ps (which include conventional tissues, eye tissues, hematopoetic stem cells/progenitor cells, and reproductive cells and tissues), and an estimated total of 2,066,890 non-reproductive cells and tissues (total HCT/Ps minus reproductive cells and tissues) are distributed per year by an estimated 1,551 establishments (2,218 − 667 = 1,551) with approved applications).

Under § 1271.60(c) and (d)(2), FDA estimates that 1,375 establishments shipped an estimated 572,000 HCT/P under quarantine, and that an estimated 25 establishments requested 78 exemptions from or alternative to any requirement under part 1271, subpart C or D, specifically under § 1271.155(a).

Under §§ 1271.290(c) and 1271.370(b) and (c), the estimated 1,561 non-reproductive HCT/P establishments label each of their 2,066,890 HCT/Ps with certain information. These establishments are also required to inform their consignees in writing of the requirements for tracking and of their established tracking system under § 1271.290(f).

FDA estimates 34 HCT/P establishments submitted 166 adverse reaction reports with 136 involving a communicable disease (§ 1271.350(a)(1)).

FDA estimates that 182 new establishments will create SOPs, and that 2,218 establishments will review and revise existing SOPs annually.

FDA estimates that 1,109 HCT/P establishments (2,218 × 50 percent = 1,109) and 781 non-reproductive HCT/P establishments (1,561 × 50 percent = 781) record and justify a departure from the procedures (§§ 1271.47(d) and 1271.265(c)(3)).

Under § 1271.50(a), HCT/P establishments are required to have a documented medical history interview about the donor's medical history and relevant social behavior as part of the

donor's relevant medical records for each of the estimated total of 109,019 donors (which include conventional tissue donors, eye tissue donors, peripheral and cord blood stem cell donors, and reproductive cell and tissue donors), and the estimated total of 103,419 non-reproductive cells and tissue donors (total donors minus reproductive cell and tissue donors).

FDA estimates that 665 HCT/P establishments (2,218 × 30 percent = 665) document an urgent medical need of the product to notify the physician using the HCT/P (§§ 1271.60(d)(3) and 1271.65(b)(3)).

FDA also estimates that 1,774 HCT/P establishments (2,218 × 80 percent = 1,774) have to maintain records for an average of 2 contract establishments to perform their manufacturing process (§ 1271.270(e), and 1,249 HCT/P establishments (1,561 × 80 percent = 1,249) maintain an average of 5 complaint records annually (§ 1271.320(b)).

In some cases, the estimated burden may appear to be lower or higher than the burden experienced by individual establishments. The estimated burden in these charts is an estimated average burden, taking into account the range of impact each regulation may have.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [3]
1271.10(b)(1) and 1271.21(b) [2]	2,218	1	2,218	.5 (30 minutes)	1,109
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b) [2]	182	1	182	.75 (45 minutes)	137
1271.10(b)(2), 1271.21(c)(2)(ii) and 1271.25(c) [2]	1,221	1	1,221	.5 (30 minutes)	611
1271.26 [2]	588	1	588	.25 (15 minutes)	147
1271.155(a)	25	3.12	78	3	234
1271.350(a)(1) and (a)(3)	34	4.88	166	1	166
Total					2,404

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Using Form FDA 3356.
[3] Rounded to the nearest whole number.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of record-keepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [3]
New SOPs [2]	182	1	182	48	8,736
SOP Update [2]	2,218	1	2,218	24	53,232
1271.47(d)	1,109	1	1,109	1	1,109
1271.50(a)	2,218	49.15	109,019	5	545,095
1271.55(d)(1)	2,218	49.15	109,019	1	109,019
1271.55(d)(2)	2,218	1	2,218	1	2,218
1271.55(d)(4)	2,218	1	2,218	120	266,160
1271.60(d)(3) and (d)(4) 1271.65(b)(3)(iii)	665	1	665	2	1,330
1271.155(f)	25	3.12	78	.25 (15 minutes)	20
1271.160(b)(3) and (b)(6)	1,561	12	18,732	1	18,732
1271.160(d)	1,561	12	18,732	1	18,732
1271.190(d)(2)	1,561	12	18,732	1	18,732
1271.195(d)	1,561	12	18,732	1	18,732
1271.200(e)	1,561	12	18,732	1	18,732
1271.210(d)	1,561	12	18,732	1	18,732
1271.230(a)	1,561	12	18,732	1	18,732
1271.230(c)	1,561	1	1,561	1	1,561
1271.260(d)	1,561	12	18,732	.25 (15 minutes)	4,683
1271.260(e)	1,561	365	569,765	.083 (5 minutes)	47,291
1271.265(c)(1)	1,561	1,324.08	2,066,890	.083 (5 minutes)	171,552
1271.265(c)(3)	781	1	781	1	781
1271.265(e)	1,561	1,324.08	2,066,890	.083 (5 minutes)	171,552
1271.270(a)	1,561	1,324.08	2,066,890	.25 (15 minutes)	516,723
1271.270(e)	1,774	2	3,548	.5 (30 minutes)	1,774
1271.290(d) and (e)	1,561	66.25	103,419	.25 (15 minutes)	25,855
1271.320(b)	1,249	5	6,245	1	6,245
Total					2,066,060

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a), 1271.250(a), and 1271.265(e).
[3] Rounded to the nearest whole number.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1271.55(a)	1,551	1,422.88	2,206,890	.5 (30 minutes)	1,103,445
1271.60(c) and (d)(2)	1,375	416	572,000	.5 (30 minutes)	286,000
1271.290(c)	1,561	1,324.08	2,066,890	.083 (5 minutes)	171,552
1271.290(f)	1,561	1	1,561	1	1,561
1271.370(b) and (c)	1,561	1,324.08	2,066,890	.25 (15 minutes)	516,723
Total					2,079,281

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

Dated: August 31, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21351 Filed 9–6–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1486]

Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as requested by Viracor-IBT Laboratories, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of July 19, 2016.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the