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**SUPPLEMENTARY INFORMATION:** It has been determined that approximately \$1,230,022 in LIHEAP funds may be available for reallocation during FY 2016. This determination is based on FY 2015 Carryover and Reallocation Reports that showed that seven grantees reported reallocation funds (Tennessee, Puerto Rico, Coyote Valley Band of Pomo Indians, Eastern Shoshone Tribe, Passamaquoddy Tribe at Pleasant Point, Poarch Band of Creek Indians, and The Klamath Tribes). Grantees submitted the FY 2015 Carryover and Reallocation Reports to the Office of Community Services (OCS), as required by regulations applicable to LIHEAP at 45 CFR 96.82. This amount, however, may increase because, as of April 1, 2016, the report for 68 grantees remains pending.

The statute allows grantees who have funds unobligated at the end of the federal fiscal year for which they are awarded to request that they be allowed to carry over up to 10 percent of their allotments to the next federal fiscal year. Funds in excess of this amount must be returned to HHS and are subject to reallocation under section 2607(b)(1) of the Act (42 U.S.C. 8626(b)(1)). The amount described in this notice was reported as unobligated FY 2015 funds in excess of the amount that these grantees could carry over to FY 2016.

OCS contacted each of the grantees to confirm that the FY 2015 funds indicated in the chart may be reallocated. In accordance with section 2607(b)(3) of the Act (42 U.S.C. 8626(b)(3)), comments will be accepted for a period of 30 days from the date of publication of this notice.

After considering any comments submitted, the Chief Executive Officers of LIHEAP grantees will be notified of the final reallocation amount. This decision will be published in the **Federal Register**.

If funds are reallocated, they will be allocated in accordance with section 2604 of the Act (42 U.S.C. 8623) and must be treated by LIHEAP grantees receiving them as an amount appropriated for FY 2016. As FY 2016 funds, they will be subject to all requirements of the Act, including section 2607(b)(2) (42 U.S.C. 8626(b)(2)), which requires that a grantee obligate at least 90 percent of its total block grant allocation for a fiscal year by the end of the fiscal year for which the funds are appropriated, that is, by September 30, 2016.

#### ESTIMATED REALLOTMENT AMOUNTS OF FY 2015 LIHEAP FUNDS

Grantee name	FY 2015 reallocation amount
Tennessee .....	\$271,910
Puerto Rico .....	818,566
Coyote Valley Band of Pomo Indians .....	9,025
Eastern Shoshone Tribe .....	37,413
Passamaquoddy Tribe at Pleasant Point .....	33,602
Poarch Band of Creek Indians ...	50,978
The Klamath Tribes .....	8,528
<b>Total .....</b>	<b>1,230,022</b>

**Statutory Authority:** 42 U.S.C. 8626.

**Mary M. Wayland,**

*Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.*

[FR Doc. 2016-13217 Filed 6-3-16; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2015-N-3432]

#### Organon USA et al.; Withdrawal of Approval of 67 New Drug Applications and 128 Abbreviated New Drug Applications; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of October 13, 2015 (80 FR 61426). The document announced the withdrawal of approval of 67 new drug applications (NDAs) and 128 abbreviated new drug applications from multiple applicants, effective November 12, 2015. The document indicated that FDA was withdrawing approval of the following two NDAs after receiving a request from the NDA holder, Merck Sharp & Dohme Corp. (Merck), 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889: NDA 016096, MINTEZOL (thiabendazole) Tablets, and NDA 016097, MINTEZOL (thiabendazole) Oral Suspension. Before withdrawal of these NDAs became effective, Merck informed FDA that it did not want approval of the NDAs withdrawn. Because Merck timely requested that approval of these NDAs not be withdrawn, the approval of NDAs 016096 and 016097 is still in effect.

**FOR FURTHER INFORMATION CONTACT:** Florine Purdie, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of Tuesday, October 13, 2015, appearing on page 61426 in FR Doc. 2015-25922, the following correction is made:

On page 61426, in table 1, the entries for NDAs 016096 and 016097 are removed.

Dated: May 31, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-13182 Filed 6-3-16; 8:45 am]

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA-2013-N-0797]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation

**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 relating to FDA regulations for human tissue intended for transplantation.

**DATES:** Submit either electronic or written comments on the collection of information by August 5, 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-0797 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation." 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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto: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 Tissue Intended for Transplantation—21 CFR Part 1270 (OMB Control Number 0910-0302)—Extension

Under section 361 of the Public Health Services Act (42 U.S.C. 264), FDA issued regulations under part 1270 (21 CFR part 1270) to prevent the transmission of human immunodeficiency virus, hepatitis B, and hepatitis C, through the use of human tissue for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet provisions intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed.

Section 1270.31(a) through (d) requires written procedures to be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process under § 1270.21; (2) all significant steps for obtaining, reviewing, and assessing the relevant medical records of the donor as prescribed in § 1270.21; (3) designating and identifying quarantined tissue; and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Sections 1270.31(a) and (b) also requires recording and justification of any deviation from the written procedures. Section 1270.33(a) requires records to be maintained concurrently with the performance of each significant step required in the performance of infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records to be retained regarding the determination of the suitability of the donors and of the records required under § 1270.21. Section 1270.33(h) requires all records to be retained for at least 10 years beyond the date of transplantation if

known, distribution, disposition, or expiration of the tissue, whichever is the latest. Section 1270.35(a) through (d) requires specific records to be maintained to document the following: (1) The results and interpretation of all required infectious disease tests; (2) information on the identity and relevant medical records of the donor; (3) the receipt and/or distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue intended for transplantation. Based on information from the Center for Biologics Evaluation and Research's (CBER's) database system, FDA estimates that there are approximately 383 tissue establishments of which 262 are conventional tissue banks and 121 are eye tissue banks. Based on information provided by industry, there are an estimated total of 2,141,960 conventional tissue products and 130,987 eye tissue products distributed per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition,

there are an estimated 29,799 deceased donors of conventional tissue and 70,027 deceased donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirements in part 1270. Based on information provided by CBER's database system, 90 percent of the conventional tissue banks are members of AATB (262 × 90% = 236), and 95 percent of eye tissue banks are members of EBAA (121 × 95% = 115). Therefore, recordkeeping by these 351 establishments (236 + 115 = 351) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 32 establishments, which is 8.36 percent of all establishments (383 – 351 = 32, or 32/383 = 8.36%).

FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, their information

collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures under § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h) include documenting the results and interpretation of all required infectious disease tests and results and the identity and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of total annual records and hours per record are based on information provided by industry and FDA experience.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
1270.31(a), (b), (c), and (d) <sup>2</sup>	32	1	32	24	768
1270.31(a) and 1270.31(b) <sup>3</sup>	32	2	64	1	64
1270.33(a), (f), and (h), and 1270.35(a) and (b)	32	6,198.84	198,363	1.0	198,363
1270.35(c)	32	11,876.12	380,036	1.0	380,036
1270.35(d)	32	1,454.50	47,504	1.0	47,504
Total					626,735

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Review and update of standard operating procedures (SOPs).

<sup>3</sup> Documentation of deviations from SOPs.

Dated: May 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-13224 Filed 6-3-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-1284]

**Determination That APRESOLINE (Hydralazine Hydrochloride) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993-0002, 301-796-8363, [Stacy.Kane@fda.hhs.gov](mailto:Stacy.Kane@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.