Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In November 2024, the ICH Assembly endorsed the draft guideline entitled ''E6(R3) Good Clinical Practice: Annex 2'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Efficacy Expert Working Group of the ICH. FDA and the Efficacy Expert Working Group will consider comments on this draft.

The draft guidance provides guidance on good clinical practices for trial design and conduct, with a focus on trials with decentralized and pragmatic elements as well as trials that utilize real-world data. Since the original E6 guidance was published in 1996, clinical trials have evolved significantly with new designs and technological innovations. Annex 2 provides additional considerations to the previously published draft guidance entitled ''E6(R3) Good Clinical Practice (GCP),'' which includes a Principles document and Annex 1. This draft guidance, entitled ''E6(R3) Good Clinical Practice: Annex 2,'' is intended to be read and implemented with E6(R3) Principles and Annex 1.

This draft guidance has been left in the original ICH format. The final guidance will be reformatted and edited to conform with FDA's good guidance practices regulation (21 CFR 10.115) and style before publication. The draft guidance, when finalized, will represent the current thinking of FDA on ''E6(R3) Good Clinical Practice: Annex 2.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3502). The collections of information in 21 CFR part 312.145 pertaining to good clinical practices have been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 pertaining to protection of human subjects, institutional review boards, and informed consent have been approved under OMB control number 0910–0130. The collections of information in 21 CFR part 11 pertaining to electronic records and electronic signatures have been approved under OMB control number 0910–0303.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.regulations.gov, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31275 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5702]

Transfer of Regulatory Responsibility From the Center for Devices and Radiological Health to the Center for Biologics Evaluation and Research; Medical Maggots and Medicinal Leeches

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; announcement of transfer.

SUMMARY: The Food and Drug Administration (FDA) is announcing the transfer of regulatory responsibility for medical maggots and medicinal leeches to the Center for Biologics Evaluation and Research (CBER). These products are currently regulated by the Center for Devices and Radiological Health (CDRH). FDA is transferring regulatory responsibility of these products to CBER because these products are living organisms that more closely align with products regulated by CBER. This action affects only Center assignment and does not change requirements applicable to these products.

DATES: FDA is transferring regulatory responsibility to CBER on December 30, 2024.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 301–796–8930, *annette.marthaler@fda.hhs.gov* or *combination@fda.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the transfer of regulatory responsibility for medical maggots (*Phaenicia sericacta* (blow fly) larvae) and medicinal leeches (*Hirudo medicinalis*) from CDRH to CBER. Medical maggots (including maggots and larvae) (product code NQK) (also referred to as maggot therapy) are harvested and provided disinfected for use in debriding non-healing necrotic skin and soft tissue wounds, including pressure ulcers, venous stasis ulcers, neuropathic foot ulcers, and non-healing traumatic or post-surgical wounds. Medicinal leeches (product code NRN) belong to the *Annelida* worm classification. The animal is a bloodsucking aquatic animal living in fresh water indicated as an adjunct to graft tissue healing when problems of venous congestion may delay healing, or to overcome the problem of venous congestion by creating prolonged localized bleeding.

FDA is transferring the regulatory responsibility for medical maggots and medicinal leeches to CBER so that these products are regulated by the same Center that regulates other living organisms for human use. The transfer will help ensure the consistent and effective regulation of products that are living organisms for human use. This transfer affects only Center assignment and does not change requirements applicable to these products.

For the transferred products, submissions, communications, and required reports should be directed to CBER after December 30, 2024. CDRH will continue to handle submissions

received (including those under review or on hold) until the publication date of this **Federal Register** document for transferred products and, if applicable, until a final decision on the submission is reached. For questions on any submissions with CDRH, please contact CDRH Product Jurisdiction at *CDRHProductJurisdiction@fda.hhs.gov.* For questions on submissions to CBER, please contact *CBERProductJurisdiction@fda.hhs.gov.*

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31266 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3248]

Fosun Pharma USA Inc., et al.; Withdrawal of Approval of 23 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** on July 29, 2024. The document announced the withdrawal of approval of 23 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 28, 2024. The document indicated that FDA was withdrawing approval of the ANDAs 073462 for tolmetin sodium capsules, equivalent to (EQ) 400 milligrams (mg) base; 073588 for tolmetin sodium tablets, EQ 200 mg base; 074002 for tolmetin sodium tablets, EQ 600 mg base; 077040 for citalopram hydrobromide tablets, EQ 10 mg base, EQ 20 mg base; EQ 40 mg base; 085787 for trifluoperazine hydrochloride (HCl) concentrate, EQ 10 mg base/milliliters (mL); 086808 for cyproheptadine HCl tablets, 4 mg; 087774 for phenylbutazone capsules, 100 mg; and 088602 for pseudoephedrine HCl; triprolidine HCl tablets, 60 mg/2.5.mg, held by Fosun Pharma USA Inc., 104 Carnegie Center, Suite 204, Princeton, NJ 08540. Additionally, ANDAS 075631 for ketorolac tromethamine injectable, 15 mg/mL and 30 mg/mL; 076427 for milrinone lactate injectable, EQ 1 mg base/mL; 076791 for haloperidol lactate injectable, EQ 5 mg base/mL; 076828 haloperidol lactate injectable, EQ 5 mg base/mL; 077947 for fluconazole injectable, 200 mg/100 mL (2 mg/mL) and 400 mg/200 mL (2 mg/mL); 078197 for granisetron HCl injectable, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL); 091436 for levofloxacin injectable, EQ 500 mg/20 mL (EQ 25 mg/mL); 207101 for sumatriptan succinate injectable, EQ 6 mg base/0.5 mL (EQ12 mg base/mL); and 215065 for methocarbamol solution, 1gram/10 mL (100 mg/mL), held by Baxter Healthcare Corp., One Baxter Parkway, Deerfield, IL 60015; and the ANDAs 090367 for levofloxacin tablets, 250 mg, 500 mg, 750 mg; and 211959 for clobazam tablets, 10 mg and 20 mg, held by Celltrion USA, Inc., U.S. Agent for Celltrion, Inc., One Evertrust Plaza, Suite 1207, Jersey City, NJ 07302; and the ANDA 212053 for chlorzoxazone tablet, 375 mg and 750 mg, held by i3 Pharmaceuticals LLC, 200 Park Ave., Warminster, PA 18974. Before FDA withdrew the approval of these ANDAs, Fosun Pharma USA Inc.; Baxter Healthcare Corp.; Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.; and i3 Pharmaceuticals LLC, 200 Park Ave., Warminster, PA 18974, informed FDA that they did not want the approval of the ANDAs withdrawn. Because Fosun Pharma USA Inc.; Baxter Healthcare Corp.; Celltrion USA, Inc., U.S. Agent for Celltrion, Inc.; and i3 Pharmaceuticals, LLC, timely requested that approval of their respective ANDAs not be withdrawn, the approvals are still in effect. This notice corrects these errors.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Monday, July 29, 2024 (89 FR 60902), appearing on page 60902 in FR Doc. 2024–16627, the following correction is made:

On page 60902, in the table, the entries for ANDA 073462, ANDA 073588, ANDA 074002, ANDA 075631, ANDA 076427, ANDA 076791, ANDA 076828, ANDA 077040, ANDA 077947, ANDA 078197, ANDA 085787, ANDA 086808, ANDA 087774, ANDA 088602, ANDA 090367, ANDA 091436 ANDA 207101, ANDA 211959, ANDA 212053, and ANDA 215065 are removed.

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31307 Filed 12–27–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Update to the Health Resources and Services Administration-Supported Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) published a **Federal Register** Notice on October 22, 2024, with proposed updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines). The proposed updates specifically relate to recommendations for Screening and Counseling for Intimate Partner and Domestic Violence, Breast Cancer Screening for Women at Average Risk, and Patient Navigation Services for Breast and Cervical Cancer Screening. Recommendations to update the Guidelines are developed by the Women's Preventive Services Initiative (WPSI) for consideration by HRSA. WPSI convenes expert health professionals to conduct rigorous reviews of the evidence following the National Academy of Medicine standards for establishing foundations for and rating strengths of recommendations, articulation of recommendations, and external reviews and it develops draft recommendations for HRSA's consideration. After consideration of public comment, HRSA has accepted the recommendations as revised and detailed in this notice. Under applicable law, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for certain preventive services, including those provided for in the HRSA-supported Guidelines. The Departments of Labor, Health and Human Services, and the Treasury have previously issued regulations describing how group health plans and health insurance issuers apply the coverage requirements. Please see *https://www.hrsa.gov/womens-guidelines* for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly Sherman, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–2170, email: *wellwomancare@hrsa.gov.*