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 **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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.

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