4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0842]

Consolidation of Wound Care Products Containing Live Cells

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is transferring oversight responsibilities for certain wound care products containing live cells from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER). This consolidation initiative provides the opportunity to further develop and coordinate scientific and regulatory activities between CDRH and CBER. FDA believes that as more wound care products containing live cells are developed such consolidation is necessary for both efficient and consistent Agency action.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5130, Silver Spring, MD 20993, 301-796-8930, john.weiner@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Consolidation of Approved Wound Care Products Containing Live Cells in CBER

On [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], primary responsibility for regulating the following approved products: P950032, P960007, P000036, P010016, (all with product code MGR); H990013 (product code PBD); and H990002 (product code OCE), and all supplements included therein, was transferred from the Office of Device

Evaluation, CDRH, to the Office of Cellular, Tissue and Gene Therapies, CBER. The jurisdictional assignment of these products to CBER is in accordance with section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) and 21 CFR 3.4. This will consolidate primary responsibility for regulating wound care products containing live cells in CBER.

II. Web Page Listing CDRH Applications Transferred to CBER and Contact Information

FDA has created a Web page listing the premarket approval applications and humanitarian device exemptions in CDRH that are being transferred to CBER. Sponsors of these products are encouraged to consult the Web page to find new contact information. The Web page address is: http://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm356173.htm.

Commencing immediately, submitters should send submissions to: Document Control Center, HFM-99, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Contact for questions on submissions: Patrick Riggins, Office of Cellular, Tissue and Gene Therapy, Center for Biologics Evaluation and Research, WOC1, rm. 234N (HFM-705), 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-5366, patrick.riggins@fda/hhs.gov.

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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