4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-P-1107]

OXIPLEX/SP Gel; FzioMed, Incorporated's Petition for Review of the Food and Drug Administration's Denial of Premarket Approval; Notice of Meeting Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Medical Devices Dispute Resolution Panel scheduled for June 10, 2014, is cancelled. This meeting was announced in the Federal Register of May 14, 2014.

FOR FURTHER INFORMATION CONTACT: Pamela D. Scott, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 3611, Silver Spring, MD 20993-0002, 301-796-5433, FAX: 301-847-8510, email: pamelad.scott@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The meeting of the Medical Devices Dispute Resolution Panel (the panel) of the Medical Devices Advisory Committee scheduled for June 10, 2014, is cancelled. On June 10, 2014, the panel was slated to discuss the Center for Device and Radiological Health's (CDRH's) denial of a premarket approval application (PMA) for OXIPLEX submitted by FzioMed, the sponsor for OXIPLEX.

On August 21, 2007, FzioMed submitted a PMA (PMA P070023) for OXIPLEX. OXIPLEX is an absorbable, clear, viscoelastic gel designed to be applied in the lower back during lumbar spine surgery. The device's proposed indication is for use as a surgical adjuvant in adult patients with primary leg pain and severe baseline back pain undergoing first surgical intervention (i.e., open or endoscopic posterior lumbar laminectomy, laminotomy, or

discectomy) for diagnosed unilateral herniation of lumbar intervertebral disc material associated with radiculopathy. The proposed intended use is for one-time use, up to 3 milliliters, after hemostasis during wound closure, as an adjunct to primary surgical intervention to improve patient outcomes by reducing leg pain, back pain, and neurologic symptoms.

On October 9, 2012, CDRH issued a decision upholding a not approvable letter in response to the PMA P070023 for OXIPLEX. CDRH determined that PMA P070023 is not approvable based on its conclusion that the data and information offered in support of the PMA do not provide a reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling, as required by section 515(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(2)).

On November 5, 2012, FzioMed requested administrative review of CDRH's decision to uphold its not approvable letter. Submitted in the form of a petition for reconsideration under 21 CFR 10.33 (see § 814.44(f)(2) (21 CFR 814.44(f)(2)), FzioMed's petition for review (petition) stated that, in accordance with § 814.44(f), FzioMed considered the decision to uphold the not approvable letter to be a denial of approval of PMA P070023 under § 814.45). Under section 515(d)(4) of the FD&C Act, FzioMed requested review of this denial under section 515(g)(2) of the FD&C Act.

Accordingly, as required by § 814.45(e)(3), CDRH issued an order denying approval of the PMA for OXIPLEX on October 21, 2013. Under section 515(g)(2) of the FD&C Act, on October 25, 2013, FDA granted FzioMed's petition for review of the order denying PMA P070023. In the Federal Register of May 14, 2014 (79 FR 27623), the Office of the Commissioner referred PMA P070023 and the basis for the order denying its approval to the

Medical Devices Dispute Resolution Panel, and announced that the panel was scheduled to meet to discuss the clinical and scientific issues raised by CDRH's Denial Order on June 10, 2014.

Since the panel meeting announcement on May 14, 2014, the parties have agreed that the panel meeting should not go forward on June 10, 2014. The Agency is thereby cancelling the June 10, 2014, meeting.

Dated: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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