

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E-0849]

Determination of Regulatory Review Period for Purposes of
Patent Extension; VITREON; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending its determination regarding the regulatory review period for purposes of patent extension for VITREON that appeared in the **Federal Register** of December 17, 1998 (63 FR 69633). FDA is amending the document because the agency agrees with the information provided in a request from the applicant for revision of the regulatory review period.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In its application for patent term extension, the applicant claimed November 10, 1989, as the date the investigational new drug (IND) application for VITREON (IND 33,858) was initially submitted. FDA records showed that IND 33,858 became effective on November 10, 1989, but upon reviewing the application, FDA determined that VITREON should be regulated as a device, not a drug, and transferred the application to the Center for Devices and Radiological Health (CDRH) on April 13, 1990. The application was renumbered as an investigational device exemption (IDE) application (IDE G900050). FDA's initial determination of the regulatory review period for VITREON used April 13, 1990, as the effective date for the investigational application (63 FR 69633, December 17, 1998). However, the applicant later claimed in its request for a revision of the regulatory review period dated February 16, 1999 (Docket No. 98E-0489), that FDA's initial determination failed to take into account that the original IND became effective on November 10, 1989, because VITREON was initially considered to be a drug rather than a device. The applicant argued that FDA did not object

to the November 10, 1989, submission and that November 10, 1989, should remain valid as the effective date of the investigational application because under both the IND and IDE regulations, an investigational application becomes effective 30 days after submission unless FDA notifies the applicant. Therefore, the applicant requested that the agency correct the date the investigational application became effective to November 10, 1989, the effective date of IND 33,858.

FDA reviewed its records and confirmed that IND 33,858 became effective on November 10, 1989. This application was subsequently transferred to CDRH because the agency decided to regulate the product as a device rather than a drug. Though the transfer of IND 33,858 to IDE G900050 occurred for administrative reasons, the application was sufficiently complete to permit a substantive review. For this reason, FDA now accepts the date of November 10, 1989, submitted by the applicant in its request, as the date that the investigational application for VITREON became effective. Therefore, the applicable regulatory review period for the VITREON application is 2,883 days. Of this time, 757 days occurred during the testing phase of the regulatory review period, while 2,126 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: November 10, 1989. November 10, 1989, is the date that IND 33,858 became effective. The application was subsequently transferred to CDRH because FDA decided to regulate VITREON as a device rather than a drug. IND 33,858 was renumbered as IDE G900050 on April 13, 1990. This transfer occurred only for administrative reasons because IND 33,858, later designated IDE G900050, was sufficiently complete to permit a substantive review. For this reason, FDA accepts the date of November 10, 1989, as the date that a clinical investigation involving this device was begun.

2. The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e): December 6, 1991. FDA has verified the applicant's claim that the premarket approval application (PMA) for VITREON (PMA P910068) was initially submitted December 6, 1991.

3. The date the application was approved: September 30, 1997. FDA has verified the applicant's claim that PMA P910068 was approved on September 30, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office

applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Any interested person may petition FDA, on or before [insert date 180 days after date of publication in the **Federal Register**], for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit one copy.

Comments

are to be identified with the docket number found in brackets in

the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: _____.

Jane A. Axelrad
Associate Director for Policy
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