



Food and Drug Administration
Rockville MD 20857

Re: Lea's Shield
Docket No.: 02E-0342

JUN 24 2001

The Honorable Jon Dudas
Acting Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Acting Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 4,703,752, filed by Shlome Gabbay, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Lea's Shield, the medical device claimed by the patent.

The total length of the regulatory review period for Lea's Shield is 5,596 days. Of this time, 5,418 days occurred during the testing phase and 178 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act involving this device became effective: November 19, 1986.

FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on November 19, 1986.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: September 18, 2001.

FDA has verified the applicant's claim that the premarket approval application (PMA) for Lea's Shield (PMA P010046) was initially submitted on September 18, 2001.

3. The date the application was approved: March 14, 2002.

FDA has verified the applicant's claim that PMA P010046 was approved on March 14, 2002.

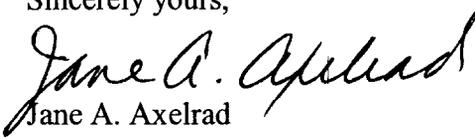
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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,



Jane A. Axelrad

Associate Director for Policy

Center for Drug Evaluation and Research

cc: Gary Pitzer, Esq.
Tarrowli, Sundheim, Covell & Tummino, L.L.P.
Suite 1111
526 Superior Avenue
Cleveland, OH 44114