



Food and Drug Administration
Rockville MD 20857

July 06, 1999

Elliott Farber, PhD
E F Associates
1720 Drive North
north Mankato, MN 56003

Dear Dr. Farber:

Your petition requesting the Food and Drug Administration to reclassify ocular prosthetic (artificial eye) lubricant was received by this office on 06/25/99. It was assigned docket number 99P-2172/CCP 1 and it was filed on 06/25/99. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script that reads "Jennie C. Butler".

Jennie C. Butler
Dockets Management Branch

99P-2172

ACK1

E F Associates
1720 Orchid Drive North
North Mankato, MN 56003
Phone (507) 387-2023
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JUN 25 9 26 AM '99

Elliott Farber, Ph.D.

April 26, 1999

Food and Drug Administration
Document Mail Center (HFZ-401)
5600 Fishers Lane
Rockville, MD 20857

To Whom It May Concern:

It is requested that the Food and Drug Administration reclassify an ocular prosthetic (artificial eye) lubricant from a Class III to a Class II Medical Device under the 513(e) Petition.

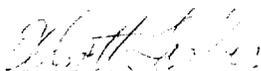
An artificial eye is fitted into an eye socket after the tissue has healed from the surgery that removed the eye. The ocular prosthetic is, in reality, a cosmetic device to improve one's physical appearance. It is not a device which is life threatening or potentially hazardous to life. As such, it should not be necessary to conduct clinical trials on this type of device.

The main concerns for the safety and effectiveness of an artificial eye lubricant are to minimize the chance of infection and be reasonably assured the lubricant is non-toxic and is non-irritating. The less stringent class requirements mandated in reclassifying an artificial eye lubricant to a Class II Medical Device will be sufficient to reasonably assure safety and effectiveness if the following performance standards are set:

1. Sterility
2. Non-toxic
3. Non-irritating

Sterility of the artificial eye lubricant is necessary to minimize the possibility of infection. The establishment of non-toxicity and non-irritating as performance standards for an artificial eye lubricant ensures the reasonable safety and effectiveness of such a device.

Sincerely,



Elliott Farber, Ph.D.
1720 Drive North
North Mankato, MN 56003
Phone (507) 387-2023

99P-2172

FDA/CDRH/OCE/DMC
JUN 23 3 55 PM '99

CCP 1

SUPPLEMENTAL DATA SHEET

1. GENERIC TYPE OF DEVICE

Lubricant For Artificial Eyes

2. ADVISORY PANEL

3. IS DEVICE AN IMPLANT?

Yes No

4. INDICATIONS FOR USE PRESCRIBED, RECOMMENDED, OR SUGGESTED IN THE DEVICE'S LABELING THAT WERE CONSIDERED BY THE ADVISORY

See Attachment.

5. IDENTIFICATION OF ANY RISKS TO HEALTH PRESENTED BY DEVICE

General None.

Specific Hazards to Health

Characteristics or Features of Device Associated with Hazard

a. _____
b. _____
c. _____
d. _____

a. _____
b. _____
c. _____
d. _____

6. RECOMMENDED ADVISORY PANEL CLASSIFICATION AND PRIORITY

Classification _____ Priority (Class II or III Only) _____

7. IF DEVICE IS AN IMPLANT, OR IS LIFE-SUSTAINING OR LIFE-SUPPORTING AND HAS BEEN CLASSIFIED IN A CATEGORY OTHER THAN CLASS III, EXPLAIN FULLY, THE REASONS FOR THE LOWER CLASSIFICATION WITH SUPPORTING DOCUMENTATION AND DATA

8. SUMMARY OF INFORMATION, INCLUDING CLINICAL EXPERIENCE OR JUDGMENT, UPON WHICH CLASSIFICATION RECOMMENDATION IS BASED

If the artificial eye lubricant is sterile, non-toxic and non-irritating, there is reasonable assurance for its safety and effectiveness.

9. IDENTIFICATION OF ANY NEEDED RESTRICTIONS ON THE USE OF THE DEVICE

Discontinue use if irritation is noted.

ATTACHMENT

1. Apply 1-2 drops about 3 times daily without removing the artificial eye; blink to spread evenly. Rub excess into skin of both lids. Remove any excess with cleansing tissue.
2. Remove accumulated discharges with a dampened cotton-tipped applicator with minimal rubbing by gently pulling lower lid downward.
3. Upon removing the artificial eye for any reason:
 - a) Wash hands thoroughly and completely rinse off.
 - b) Wash artificial eye using fingertips and rinse thoroughly.
 - c) Dry artificial eye with cleansing tissue. Apply one drop of lubricant to front and back surfaces.
 - d) Replace eye. Add an additional drop externally and blink to spread evenly.

If irritation occurs, discontinue use and consult your doctor.

10. IF DEVICE IS IN CLASS I, RECOMMEND WHETHER FDA SHOULD EXEMPT IT FROM

Justification / Comments

- a. Registration / Device Listing _____
- b. Premarket Notification _____
- c. Records and Reports _____
- d. Good Manufacturing Practice _____

11. EXISTING STANDARDS APPLICABLE TO THE DEVICE, DEVICE SUBASSEMBLIES (*Components*) OR DEVICE MATERIALS (*Parts and Accessories*)

Sterile, Non-toxic, Non-irritating.

12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO:

Food and Drug Administration
Center for Devices and Radiological Health
Office of Health and Industry Programs (HFZ-215)
1350 Piccard Drive
Rockville, MD 20850

OMB STATEMENT

Public reporting burden for this collection of information is estimated to average 1-2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer, Paperwork Reduction Project (0910-0138)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

(Please DO NOT RETURN this form to this address.)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION
GENERAL DEVICE CLASSIFICATION QUESTIONNAIRE

FORM APPROVED: OMB NO. 0910-0138
EXPIRATION DATE: January 1, 2000
(See OMB Statement on Page 2)

~~PREMARKET APPROVAL~~ / PETITIONER

Elliott Farber

DATE

April 26, 1999

GENERIC TYPE OF DEVICE

Lubricant For Artificial Eyes

CLASSIFICATION RECOMMENDATION

II

1. IS THE DEVICE LIFE-SUSTAINING OR LIFE-SUPPORTING ?

YES NO

Go to Item 2.

2. IS THE DEVICE FOR A USE WHICH IS OF SUBSTANTIAL IMPORTANCE IN PREVENTING IMPAIRMENT OF HUMAN HEALTH ?

YES NO

Go to Item 3.

3. DOES THE DEVICE PRESENT A POTENTIAL UNREASONABLE RISK OF ILLNESS OR INJURY ?

YES NO

Go to Item 4.

4. DID YOU ANSWER "YES" TO ANY OF THE ABOVE 3 QUESTIONS ?

YES NO

If "Yes," go to Item 7.
If "No," go to Item 5.

5. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES NO

If "Yes," Classify in Class I.
If "No," go to Item 6.

6. IS THERE SUFFICIENT INFORMATION TO ESTABLISH SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ?

YES NO

If "Yes," go to Item 7.
If "No," Classify in Class I.

7. IS THERE SUFFICIENT INFORMATION TO ESTABLISH SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF SAFETY AND EFFECTIVENESS ? IF YES, CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCE. FOR CLASS II.

YES NO

If "Yes," Classify in Class II
If "No," Classify in Class III

- Postmarket Surveillance
- Performance Standard(s)
- Patient Registries
- Device Tracking
- Testing Guidelines
- Other (specify)

8. IF A REGULATORY PERFORMANCE STANDARD IS NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE, IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD.

- Low Priority _____
- Medium Priority _____
- High Priority _____
- Not Applicable _____

9. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?

YES NO
 NOT Applicable

10. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS.

- Low Priority _____
- Medium Priority _____
- High Priority _____
- Not Applicable _____

1a. CAN THERE OTHERWISE BE REASONABLE ASSURANCE OF ITS SAFETY AND EFFECTIVENESS WITHOUT RESTRICTIONS ON ITS SALE, DISTRIBUTION OR USE, BECAUSE OF ANY POTENTIALITY FOR HARMFUL EFFECT OR THE COLLATERAL MEASURES NECESSARY FOR THE DEVICE'S USE ?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	If "Yes," go to Item 12. If "No," go to Item 11b.
1b. IDENTIFY THE NEEDED RESTRICTION(S) (If Item 11a. was checked "NO.") <input type="checkbox"/> Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device <input type="checkbox"/> Use only by persons with specific training or experience in its use <input type="checkbox"/> Use only in certain facilities <input type="checkbox"/> Other (Specify) _____ _____ _____		
12. COMPLETE THIS FORM PURSUANT TO 21 CFR PART 860 AND SUBMIT TO: Food and Drug Administration Center for Devices and Radiological Health Office of Health and Industry Programs (HFZ-215) 1350 Piccard Drive Rockville, MD 20850		

OMB STATEMENT

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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE — FOOD AND DRUG ADMINISTRATION IN VITRO DIAGNOSTIC PRODUCT CLASSIFICATION QUESTIONNAIRE		FORM APPROVED: OMB NO. 0910-0138 EXPIRATION DATE: January 1, 2000 (See OMB Statement on Page 2)
RECLASSIFICATION NUMBER / PETITIONER Elliott Farber		DATE April 26, 1999
GENERIC TYPE OF DEVICE Artificial Eye Lubricant	CLASSIFICATION RECOMMENDATION II	
1. IS THE IN VITRO DIAGNOSTIC PRODUCT OR INFORMATION DERIVED FROM ITS USE POTENTIALLY HAZARDOUS TO LIFE, HEALTH, OR WELL BEING WHEN PUT TO ITS INTENDED USE ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	Go to Item 2.
2. IS THERE SUFFICIENT INFORMATION TO DETERMINE THAT GENERAL CONTROLS ARE SUFFICIENT TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF THE DEVICE ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	If "Yes," classify in Class I If "No," go to Item 3.
3a. CONSIDERING THE NATURE AND COMPLEXITY OF THE PRODUCT AND THE AVAILABLE SCIENTIFIC AND MEDICAL INFORMATION, IS THERE SUFFICIENT INFORMATION TO ESTABLISH A SPECIAL CONTROL OR SET OF SPECIAL CONTROLS TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF THE DEVICE ?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	If "Yes," Classify in Class II and go to Item 3b. If "No," Classify in Class III and go to Item 4a.
3b. CHECK THE SPECIAL CONTROL(S) NEEDED TO PROVIDE SUCH REASONABLE ASSURANCES (If "YES" to Item 3a.) <input type="checkbox"/> Postmarket Surveillance <input checked="" type="checkbox"/> Performance Standard(s) <input type="checkbox"/> Testing Guidelines <input type="checkbox"/> Device Tracking <input type="checkbox"/> Other (Specify) _____ Sterility, Non-toxic & Non-irritating	<input type="checkbox"/> YES <input type="checkbox"/> NO	
4a. IS A REGULATORY PERFORMANCE STANDARD NEEDED TO PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF A CLASS II OR III DEVICE ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NOT Applicable	
4b. IF "YES," TO ITEM 4a., IDENTIFY THE PRIORITY FOR ESTABLISHING SUCH A STANDARD. <input type="checkbox"/> Low Priority <input type="checkbox"/> Medium Priority <input type="checkbox"/> High Priority	<input checked="" type="checkbox"/> NOT Applicable	
5. FOR A DEVICE RECOMMENDED FOR RECLASSIFICATION INTO CLASS II, SHOULD THE RECOMMENDED REGULATORY PERFORMANCE STANDARD BE IN PLACE BEFORE THE RECLASSIFICATION TAKES EFFECT ?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> NOT Applicable	
6. FOR A DEVICE RECOMMENDED FOR CLASSIFICATION / RECLASSIFICATION INTO CLASS III, IDENTIFY THE PRIORITY FOR REQUIRING PREMARKET APPROVAL APPLICATION (PMA) SUBMISSIONS. <input type="checkbox"/> Low Priority <input type="checkbox"/> Medium Priority <input type="checkbox"/> High Priority <input type="checkbox"/> Not Applicable		

CLASSIFICATION QUESTIONNAIRE FORM

Medical Device Classification System

Panel Member: _____ Date: _____

Device: Lubricant For False Eyes

Use Categories: Diagnostic Monitoring Prosthetic Surgical Therapeutic Other

Regulatory Level: I. General Controls Specific device problems: Yes No
 II. Performance Standards
 III. Premarket Approval

Classification System	Yes	No	Do Not Know	Regulatory Level	Question Scheme
1. Custom Made?		XX			Yes--2 No--3
2. Custom Made: Standard?		XX			Yes No 17
3. Life-sustaining?		XX			Yes--5 No--4
4. Potentially hazardous to life, good health		XX			Yes } 5 No--7 DNK }
5. (a) Can standards be developed now; and (b) would standard be adequate?	XX	XX			Yes--7 No DNK--6
6. Marketed in U.S.?	XX				Yes } 7 No }
7. Remote from body?	XX				Yes--14 No } 8 DNK }
8. Powered?		XX			Yes--9 No--13
9. Failure of power: hazardous to patient?					Yes DNK } 10 No }
10. Introduce energy into body?					Yes--11 No--13
11. Acceptable energy levels?					Yes } 12 No }
12. Safe energy levels if malfunction?					Yes } 13 No } DNK }
13. Material regarded as safe without standard:	XX				Yes } 14 No } DNK }
14. Proscriptions needed? limitation, hazards, difficulties, problems		XX			Yes } 15 No }
15. Labeling, instructions or precautions on measurement function?	XX				Yes } 16 No }
16. Performance Standards?	XX				Yes } 17 No }
17. Special safety systems considerations?		XX			Yes } 18 No } DNK }
18. Potentially hazardous to fetus and/or gonads		XX			Yes } To DNK } 05-5vn Panel
Low Density Coding Form					

Supplementary Data Sheet
Summary of Reasons for Classification

1. Device Name Ocular Prosthetic (Artificial Eye) Lubricant

2. Classification Panel _____

3. Is device an implant? No

4. Indications for use prescribed, recommended, or suggested in the device's labeling that were considered by the panel See Attachment.

5. Identification of any risks to health presented by device

General Infection - minimized by sterilizing the device.
Toxicity potential reduced by using only a non-toxic
device. Potential for irritation is minimized by using
a non-irritating device.

Specific Hazards
to Health

Characteristic or Feature of Device
Associated with Hazard

a. _____	a. _____
b. _____	b. _____
c. _____	c. _____
d. _____	d. _____

6. Recommended panel classification and priority

Classification

Priority (Class II or III Only)

7. If device is an implant, or is life-sustaining or life-supporting, and has been classified in a category other than Class III, explain fully reasons for the lower classification with supporting documentation and data

8. Summary of data including clinical experience or judgment upon which classification recommendation is based

Sterility, non-toxic, non-irritating.

9. Identification of any needed restrictions on the use of the device

None.

10. If device is in Class I, recommend whether FDA should exempt it from:

Justification/COMMENTS

a. Registration

a. _____

b. Records and Reports

b. _____

c. Good Manufacturing Practice

c. _____

11. Existing standards applicable to the device, device subassemblies (components), or device materials (parts and accessories)

Sterility, Non-toxic, Non-irritating.

ATTACHMENT

Apply 1-2 drops about 3 times daily without removing the artificial eye; blink to spread evenly. Rub excess into skin of both lids. Remove any excess with cleansing tissue. Remove accumulated discharges with a dampened cotton-tipped applicator with minimal rubbing by gently pulling lower lid downward. Upon removing the artificial eye for any reason:

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