

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 21174

MICROBIOLOGY REVIEW(S)

Bradley

APR 12 2000

REVIEW FOR HFD-150
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA

March 12, 2000

A. 1. NDA 21-174

SPONSOR Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101-8299

2. PRODUCT NAMES: Gemtuzumab Zogamicin (Product code CMA-676). The intended tradename is "Mylotarg."

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: The product is a lyophilized powder in a 20 cc amber glass vial, for reconstitution (with 5 mL sterile Water for Injection), dilution (in 100 mL sterile 0.9% Sodium Chloride Injection), and infusion over 2 hours.

4. METHOD(S) OF STERILIZATION: []

5. PHARMACOLOGICAL CATEGORY: Oncolytic agent for treating relapsed acute myeloid leukemia

6. DRUG PRIORITY CLASSIFICATION: 1P

B. 1. DATE OF INITIAL SUBMISSION: October 29, 1999 (subject of Microbiologist's Review #1 dated March 6, 2000)

2. DATE OF AMENDMENT: March 31, 2000 (subject of this review)

3. RELATED DOCUMENTS:

<u>Document</u>	<u>Holder</u>	<u>Activity</u>
DMF [Vial supplier
DMF]		Stopper Supplier

4. ASSIGNED FOR REVIEW: April 7, 2000

C. REMARKS: The drug product is a conjugate of antibody and anti-tumor agent to treat leukemia. The product is intended to treat patients with relapsing acute myeloid leukemia

(AML). The original filing of the NDA was permitted without 12 months stability data because of the clinical importance of the product. Microbiologist's Review #1 (March 6, 2000) resulted in 2 deficiencies and 1 comment. The current submission (sent by FAX) responds to those questions. The division requesting the consult asks for a review response by April 12, 2000 to achieve the user fee goal date of April 29, 2000.

D. CONCLUSIONS: The application is recommended for APPROVAL.

JS
4-12-2000

David Hussong, Ph.D.

PHC 4/12/00

cc:

Original NDA 21-174
HFD 150/Division File
HFD 160/Consult File
HFD 150/CSO/A. Dunson
HFD 150/Bradley
HFD 150/Chemistry/X. Chen
HFD 150/Chemistry/E. Duffy
HFD 805/D. Hussong

Drafted by: D. Hussong, 04/12/2000
R/D initialed by: P. Cooney

Filename, d:\nda\21-174rv2.doc

Dunson

MAR 8 2000

REVIEW FOR HFD-150
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA

March 6, 2000

- A. 1. **NDA** 21-174
 - SPONSOR** Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101-8299
 - 2. **PRODUCT NAMES:** Gemtuzumab Zogamicin (Product code CMA-676). The intended tradename is "Mylotarg."
 - 3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** The product is a lyophilized powder in a 20 cc amber glass vial, for reconstitution (with 5 mL sterile Water for Injection), dilution (in 100 mL sterile 0.9% Sodium Chloride Injection), and infusion over 2 hours.
 - 4. **METHOD(S) OF STERILIZATION:** []
 - 5. **PHARMACOLOGICAL CATEGORY:** Oncolytic agent for treating relapsed acute myeloid leukemia
 - 6. **DRUG PRIORITY CLASSIFICATION:** 1P

- B. 1. **DATE OF INITIAL SUBMISSION:** October 29, 1999
- 2. **DATE OF AMENDMENT:** (none)
- 3. **RELATED DOCUMENTS:**

<u>Document</u>	<u>Holder</u>	<u>Activity</u>
DMF [Vial supplier
DMF]		Stopper Supplier
- 4. **ASSIGNED FOR REVIEW:** November 10, 1999

C. **REMARKS:** The drug product is a conjugate of antibody and anti-tumor agent to treat

leukemia. The product is intended to treat patients with relapsing acute myeloid leukemia (AML). The original filing of the NDA was permitted without 12 months stability data because of the clinical importance of the product. Volumes 1.1, 1.2, 1.74 and 1.75 were provided for consultative review. Volumes 1.1 and 1.2 contained general introductory information. Volumes 1.74 and 1.75 contained sterility assurance documentation.

- D. CONCLUSIONS: The application is APPROVABLE for issues relating to product quality microbiology.

/S/ 3-6-2000

David Hussong, Ph.D. 3/8/00
/S/

cc:

Original NDA 21-174
HFD 150/Division File
HFD 160/Consult File
HFD 150/CSO/A. Dunson
HFD 150/Chemistry/E. Duffy
HFD 805/D. Hussong

Drafted by: D. Hussong, 03/06/2000
R/D initialed by: P. Cooney

Filename, d:\nda\21-174rv1.doc