CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 21174

CORRESPONDENCE

DESK COPY

WYETH-AYERST RESEARCH

P.O. BOX 8299, PHILADELPHIA, PA 19101-8299 • (610) 902-3710
FAX: (610)964-5973

Division of American Home Products Corporation

U.S. REGULATORY AFFAIRS

April 21, 2000

NDA No. 21-174

Response to FDA Request:
Revised Vial and Carton Labels

Richard Pazdur, M.D., Director
Division of Oncology Drug Products (HFD-150)
Center for Drug Evaluation and Research
ATTN: Document Control Room
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852

Dear Dr. Pazdur:

Reference is made to our pending NDA No. 21-174 for Mylotarg™ (gemtuzumab ozogamicin for Injection) previously submitted to your Division on October 29, 1999.

Reference is also made to the Division's April 10, 2000 facsimile, which provided comments on the vial and carton label for Mylotarg.

The purpose of this submission is to provide draft vial and carton labels that have been revised to incorporate the Division's comments. The changes are listed below:

1. The red line through the "TARG" of MYLOTARG has been removed.

2. The font boldness for the established name has been increased on the immediate container label.

3. "Usual Dosage" has been changed to "Recommended Dosage."

4. An additional "Protect from Light" statement has been added.

5. The established name now includes "for Injection" so that it now reads "gemtuzumab ozogamicin for Injection."

6. The package has been updated from "zogamicin" to "ozogamicin."

Accordingly, we are pleased to provide as Attachment 1, one copy each of the vial and carton label.

If there are any questions regarding this submission, please contact me at (610) 902-3742.

Sincerely,

WYETH-AYERST LABORATORIES

Barry D. Sickels

Barry D. Sickels, Associate Director
Worldwide Regulatory Affairs

bds:ndalet40

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

FOR FDA USE ONLY
APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT: Wyeth-Ayerst Laboratories	DATE OF SUBMISSION: April 21, 2000
TELEPHONE NO. *(Include Area Code)*: (610) 902-3742	FACSIMILE (FAX) Number *(Include Area Code)*: (610) 964-5973
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: P.O. Box 8299 Philadelphia, PA 19101-8299	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued): NDA No. 21-174

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*: gemtuzumab ozogamicin

PROPRIETARY NAME *(trade name)* IF ANY: Mylotarg

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*: See Attachment 1

CODE NAME *(If any)*: CMA-676

DOSAGE FORM: injectable

STRENGTHS: 5 mg/vial

ROUTE OF ADMINISTRATION: I.V.

(PROPOSED) INDICATION(S) FOR USE: Treatment of relapsed acute myeloid leukemia (AML)

APPLICATION INFORMATION

APPLICATION TYPE (check one): ☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE: ☒ 505 (b) (1) ☐ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one): ☒ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☒ OTHER

REASON FOR SUBMISSION: Revised Vial and Carton Labels

PROPOSED MARKETING STATUS (check one): ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED ________

THIS APPLICATION IS ☐ PAPER ☒ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See Attachment 2

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

IND No( )

	This application contains the following items: *(Check all that apply)*
[X]	1. Index
[ ]	2. Labeling (check one) [X] Draft Labeling [ ] Final Printed Labeling
[ ]	3. Summary (21 CFR 314.50 (c))
[ ]	4. Chemistry section
[ ]	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)
[ ]	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)
[ ]	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)
[ ]	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)
[ ]	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
[ ]	7. Clinical Microbioblogy (e.g. 21 CFR 314.50 (d) (4))
[ ]	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)
[ ]	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)
[ ]	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)
[ ]	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)
[ ]	12. Case reports forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)
[ ]	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
[ ]	14. A patent certification with respect to any patent which claims the drug (21 U.S.C 355 (b) (2) or (j) (2) (A))
[ ]	15. Establishment description (21 CFR Part 600, if applicable)
[ ]	16. Debarment certification (FD&C Act 306 (k)(1))
[ ]	17. Field copy certification (21 CFR 314.50 (k) (3))
[ ]	18. User Fee Cover Sheet (Form FDA 3397)
[ ]	19. OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 21 CFR 314.80,314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.
The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.
Warning: a willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
[signature]	Barry D. Sickels Assoc. Director, Regulatory Affairs	[illegible]

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
170 Radnor Chester Road St. Davids, PA 19087	(610) 902-3742

Public reporting burden for this collection of information is estimated to average 40 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 (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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FORM FDA 356h (7/97)