CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-572

Correspondence

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR - 5 2003

Counsel to Cubist Pharmaceuticals, Inc.

RE: **Cubist Pharmaceuticals, Inc., Small Business Waiver Request — for New Drug Application 21-572 for Cidecin (daptomycin for injection)**

Dear Mr. —

This responds to your December 18, 2002, and December 31, 2002, letters on behalf of Cubist Pharmaceuticals, Inc. (Cubist) requesting a waiver of the human drug application fee for new drug application (NDA) 21-572 for Cidecin (daptomycin for injection) under the small business waiver provision of section 736(d)(1)(D)[1] of the Federal Food, Drug, and Cosmetic Act (the Act) (Waiver Request — For the reasons described below, the Food and Drug Administration (FDA) grants the request from Cubist Pharmaceuticals, Inc. (Cubist) for a small business waiver of the application fee for an NDA for Cidecin.

According to your waiver request, Cubist is a small business with fewer than 500 employees including employees of your affiliates. You also note that NDA 21-572 for Cidecin is the first human drug application submitted to FDA by Cubist for review.

Under the Act, a waiver of the application fee shall be granted to a small business for the first human drug application that a small business or its affiliate[2] submits to the FDA for review. The small business waiver provision entitles a qualified small business to a waiver when the business meets the following criteria: (1) the business must employ fewer than 500 persons, including employees of its affiliates, and (2) the marketing application must be the first human drug application, within the meaning of the Act, that a company or its affiliate submits to FDA.

FDA's decision to grant Cubist's request for a small business waiver for the NDA for Cidecin is based on the following findings. First, the Small Business Administration (SBA) determined and stated in its letter dated January 15, 2003, that Cubist has fewer than 500 employees including its affiliates:

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[1] 21 U.S.C. 379h(d)(1)(D).

[2] "The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly — (A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has the power to control, both of the business entities" (21 U.S.C. 379g(9)).

C&T Acquisition Corporation; Terragen Discovery, Inc.; Cubist Pharmaceuticals Canada, Inc.; and Cubist Pharmaceuticals UK, Ltd.

Second, according to FDA records, the marketing application for Cidecin, NDA 21-572, is the first human drug application, within the meaning of the Act, to be submitted to FDA by Cubist or any of its affiliates. Consequently, your request for a small business waiver of the application fee for NDA 21-572 Cidecin is granted, provided that FDA receives the marketing application for Cidecin no later than January 15, 2004, 1 year after the effective date of the size determination made by SBA.

If FDA refuses to file the application or Cubist withdraws the application before it is filed by FDA, a reevaluation of the waiver may be required should the company resubmit its marketing application. If this situation occurs, Cubist should contact this office approximately 90 days before it expects to resubmit its marketing application to determine whether it continues to qualify for a waiver.

We have notified the FDA Office of Financial Management (OFM) of this waiver decision and have asked them to waive the application fee for NDA 21-572. FDA records show that Cubist's NDA 21 572 was submitted on December 20, 2002, and FDA was notified of the $533,400 payment for the application on December 23, 2002. Cubist should receive a refund of $533,400. If Cubist does not receive this refund within 30 days of the date of this letter, please contact Donna Simms, OFM, at 301-827-5042.

FDA plans to disclose to the public information about its actions granting or denying waivers and reductions. This disclosure will be consistent with the laws and regulations governing the disclosure of confidential commercial or financial information.

If any billing questions arise concerning the marketing application or if you have any questions about this small business waiver, please contact Beverly Friedman, Michael Jones, or Tawni Schwemer at 301-594-2041.

Sincerely,

/S/

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

BCC:
HFD-5 M. Jones
HFD-5 B. Friedman
HFD-5 Chronological File
HFD-5 Cubist Pharmaceuticals, Inc. waiver file
HFM-110 C. Vincent/R. Eastep
HFA-103 S. Farran (RECORD ON PAYMENT AND ARREARS LIST)
HFA-120 D. Simms – (REFUND PENDING)
HF-20 F. Claunts

Drafted: B. Friedman 1/28/03
Edited: O.Pritzlaff 2/19/03
Reviewed: J. Axelrad 2/26/03
Revised punctuation: B. Friedman 2/27/03
Reviewed and signed: J. Axelrad

February 27, 2003

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commercial

information

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-572

Cubist Pharmaceuticals, Inc.
Attention: David H. Schubert
Vice President, Regulatory Affairs and Quality
65 Hayden Avenue
Lexington, MA 02421

Dear Mr. Schubert:

Please refer to your December 20, 2002 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cidecin® (daptomycin for injection) Intravenous Injection.

On June 16, 2003, we received your June 16, 2003 major amendment to this application. The receipt date is within 3 months of the user fee goal date. Therefore, we are extending the goal date by three months to provide time for a full review of the submission. The extended user fee goal date is September 20, 2003.

If you have any questions, call LTJG Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

/S/

Janice Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth
6/18/03 02:24:46 PM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-572

Cubist Pharmaceuticals, Inc.
Attention: David H. Schubert
Vice President, Regulatory Affairs and Quality
65 Hayden Avenue
Lexington, MA 02421

Dear Mr. Schubert:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Cidecin® (daptomycin for injection) Intravenous Injection

Review Priority Classification: Priority (P)

Date of Application: December 19, 2002

Date of Receipt: December 20, 2002

Our Reference Number: NDA 21-572

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on February 18, 2003 in accordance with 21 CFR 314.101(a). If we file the application, the user fee goal date will be June 20, 2003.

Under 21 CFR 314.102(c), you may request an informal conference with this Division (to be held approximately 90 days from the above receipt date) for a brief report on the status of the review but not on the ultimate approvability of the application. Alternatively, you may choose to receive a report by telephone.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. Address all communications concerning this NDA as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Product
Attention: Division Document Room, HFD-520
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Infective Drug Products, HFD-520
Attention: Document Room
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions, call LTJG Raquel Peat, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Frances LeSane
Chief, Project Management Staff
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Beth Duvall-Miller
2/19/03 11:15:11 AM
BDM acting for FVL