

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**21-572**

**Correspondence**



MAR - 5 2003

Food and Drug Administration  
Rockville MD 20857

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)<sup>1</sup> 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<sup>2</sup> 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:

<sup>1</sup> 21 U.S.C. 379h(d)(1)(D).

<sup>2</sup> "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

Cubist Pharmaceuticals, Inc.  
Waiver Request #  
Page 3

**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

\\CDS029\PDUFA\WAIVER\PENDING\Cubist\02a10112.doc

Redacted 4

pages of trade

secret and/or

confidential

commercial

information

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.