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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-572

Administrative Documents

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SUBMISSION OF PATENT INFORMATION PURSUANT TO 21 C.F.R. § 314.53

Patent No.	Expiration Date	Type of Patent	Patent Owner
5,912,226	June 15, 2016	Drug Product	Eli Lilly and Company
6,468,967	September 24, 2019	Method of Use	Cubist Pharmaceuticals, Inc.

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DECLARATION OF TIMOTHY J. DOUROS, ESQ.

The undersigned declares that U.S. Patent No. 5,912,226 covers the formulation, composition, and/or method of use of daptomycin. Daptomycin is the subject of this application no. 21 572 for which approval is being sought.

Timothy J. Douros
Chief Intellectual Property Counsel
Cubist Pharmaceuticals, Inc.

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DECLARATION OF TIMOTHY J. DOUROS, ESQ.

The undersigned declares that U.S. Patent No. 6,468,967 covers the formulation, composition, and/or method of use of daptomycin. Daptomycin is the subject of this application no. 21 572 for which approval is being sought.

Timothy J. Douros
Chief Intellectual Property Counsel
Cubist Pharmaceuticals, Inc.

EXCLUSIVITY SUMMARY for NDA #: 21-572 SUPPL #: N/A

Trade Name: Cubicin™ Generic Name: Daptomycin for injection
Applicant Name: Cubist Pharmaceuticals, Inc.
Division: HFD- 520
Approval Date: September 12, 2003

PART I: IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "YES" to one or more of the following questions about the submission.

   a) Is it an original NDA? YES/_X__/ NO /___/

   b) Is it an effectiveness supplement? YES /___/ NO /_X__/

      If yes, what type(SE1, SE2, etc.)? _____

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "NO.")

      YES /_X__/ NO /___/

      If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

      _____

      _____

      If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

      _____

      _____

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