DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-682\S-020

Merck & Company, Inc.
Attention: Kenneth Kramer
Associate Manager, Regulatory Affairs Domestic
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated March 6, 2003, received March 7, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cosmegen (Dactinomycin for Injection).

This "Changes Being Effected" supplemental new drug application provides for revised boxed WARNING and HOW SUPPLIED, Special Handling to include a caution to avoid exposure during pregnancy and revised OVERDOSAGE to include LD50 data for mouse and rat. A statement that the product is not for oral administration is proposed for DOSAGE AND ADMINISTRATION.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 6, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul Zimmerman, Regulatory Project Manager, at (301) 594-5775.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

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