**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-682/S-022

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

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated August 5, 2005, received August 8, 2005, 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 labeling changes to PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, and 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 August 5, 2005.

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}*

Robert L. Justice, M.D.
Acting Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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/s/

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Robert Justice

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