



NDA 50-682/S-019

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

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated August 22, 2002, received August 23, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cosmegen (Dactinomycin for Injection).

This supplemental new drug application provides for the addition of a Geriatric Use subsection.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the proposed labeling text.

The final printed labeling (FPL) must be identical to the submitted proposed labeling (package insert submitted August 22, 2002).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-682/S-019." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 reporting requirements for an approved NDA (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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