



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-975/S-010

Covidien  
Attention: Edward R. Porter  
Manager, Regulatory Affairs  
675 McDonnell Boulevard  
P.O. Box 5840  
St. Louis, MO 63134

Dear Mr. Porter:

Please refer to your supplemental new drug application dated January 5, 2006, received January 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for OptiMARK® Pharmacy Bulk Package Injection.

Your submission of September 28, 2007, constituted a complete response to our June 23, 2006, action letter.

This supplemental new drug application provides for changing the holding time of the product once the container closure [REDACTED]. This supplement provides for a change in holding time from [REDACTED].

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

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert) submitted September 28, 2007.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-975/S-010.**" 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 the Division of Medical Imaging and Hematology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

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  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 James Moore, Regulatory Project Manager, at (301) 796-2050.

Sincerely,

*{See appended electronic signature page}*

Libero Marzella, M.D.  
Acting Deputy Director  
Division of Medical Imaging and Hematology  
Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Libero Marzella  
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