



NDA 21-388

Bryan Corporation
C/O
Waldman Biomedical Consultancy, Inc.
P.O. Box 575
Oceanside, NY 11572

Attention: Alan Waldman, Ph.D.
President
Waldman Biomedical Consultancy, Inc.

Dear Dr. Waldman:

Please refer to your new drug application (NDA) dated September 20, 2002, received September 23, 2002, submitted pursuant to 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Sterile Talc Powder®.

We acknowledge receipt of your submissions dated April 2 and 7; July 3 and 31; August 12; September 30 (2); October 8, 15, and 20, 2003.

The July 3 and August 12, 2003 submissions constituted a complete response to our March 21, 2003 action letter.

This new drug application provides for the use of Sterile Talc Powder® for administering intrapleurally via chest-tube as a sclerosing agent to decrease the recurrence of malignant pleural effusions in symptomatic patients.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision below.

In the DOSAGE AND ADMINISTRATION section:

The recommended dose is 5 g, dissolved in 50 - 100 ml ~~sodium chloride~~ Sodium Chloride Injection, USP. Although the optimal dose for effective pleurodesis is unknown, 5 g was the dose most frequently reported in the published literature.

The final printed labeling (FPL) must be identical to the enclosed labeling submitted labeling. These revisions are terms of the NDA approval. Marketing the product(s) before making the

revisions, exactly as stated, in the product's labeling may render the product misbranded and an unapproved new drug.

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 NDA 21-388.**" Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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

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 Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation and Research 1
Center for Drug Evaluation and Research

Enclosure

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

Richard Pazdur
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