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RESEARCH**

*APPLICATION NUMBER:*

**21-716**

**APPROVAL LETTER**



NDA 21-716

PrimaPharm, Inc.  
Attention: Anthony Dziabo  
VP, Product Development and Regulatory Affairs  
3443 Tripp Court, Suite A  
San Diego, California 92121

Dear Mr. Dziabo:

Please refer to your new drug application (NDA) dated October 17, 2003, received October 20, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Hydase (hyaluronidase injection).

We acknowledge receipt of your submissions dated January 12, April 13, May 5, and June 3 and 30, 2005. The January 12, 2005, submission constituted a complete response to our April 20, 2004, action letter.

This new drug application provides for the use of Hydase (hyaluronidase injection) as an adjuvant to increase the absorption and dispersion of other injected drugs; for hypodermoclysis; and as an adjunct in subcutaneous urography for improving resorption of radiopaque agents.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels from your submission dated June 30, 2005). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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 Division of Anti-Infective and Ophthalmology Products, HFD-520, 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

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 Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

*{See appended electronic signature page}*

Mark J. Goldberger, M.D., M.P.H.  
Director  
Office of Drug Evaluation IV  
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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Mark Goldberger  
10/25/2005 12:09:19 PM