

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**202344Orig1s000**

***Trade Name:*** Binosto

***Generic Name:*** Alendronate Sodium Effervescent Tablets

***Sponsor:*** Mission Pharmaceutical

***Approval Date:*** 3/12/2012

***Indications:*** For treatment of postmenopausal osteoporosis and to increase bone mass in men with osteoporosis

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**APPROVAL LETTER**



NDA 202344

**NDA APPROVAL**

EffRx Pharmaceuticals SA  
c/o Hurley Consulting Associates Ltd.  
Attention: Susan M. Mondabaugh, Ph.D.  
Vice President Regulatory Affairs  
One Main Street  
Chatham, NJ 07928

Dear Dr. Mondabaugh:

Please refer to your New Drug Application (NDA) dated December 21, 2010, received February 15, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Binosto® (alendronate sodium) effervescent tablets, 70 mg.

We acknowledge receipt of your amendments dated, March 29 and 31, May 12, (2), and 25, June 22, and 27, July 7, 20, and 29, August 9, 22, and 25, September 8, 22, and 29, October 7, 14, 20 and 28, November 8, December 16, 2011, and January 12 and 27, February 16, 23(3), 27, and 29, March 2, 5 and 8, 2012.

This new drug application provides for the use of Binosto (alendronate sodium) effervescent tablets, 70 mg for the treatment of postmenopausal osteoporosis and to increase bone mass in men with osteoporosis.

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

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling text for the package insert, text for the patient package insert, Medication Guide. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

## **CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on March 2, 2012, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 202344.**” Approval of this submission by FDA is not required before the labeling is used.

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.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. The product’s indications of treatment of postmenopausal osteoporosis and treatment to increase bone mass in men with osteoporosis are diseases/conditions that do not exist in children.

## **RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS**

We acknowledge receipt of your submission dated December 21, 2010, of a proposed risk evaluation and mitigation strategy (REMS). We have determined that, at this time, a REMS is not necessary for BINOSTO to ensure that its benefits outweigh its risks because the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. The Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA. We will notify you if we become aware of new safety information and make a determination that a REMS is necessary.

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **REPORTING REQUIREMENTS**

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 Meredith Alpert, Regulatory Project Manager, at (301) 796-1218.

Sincerely,

*{See appended electronic signature page}*

Audrey Gassman, M.D.  
Acting Deputy Director  
Division of Reproductive and Urologic  
Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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AUDREY L GASSMAN  
03/12/2012