



NDA 203231

**TENTATIVE APPROVAL**

ACS Dobfar Info SA  
Attention: Thomas J. Moutvic  
Vice President, Regulatory Affairs  
Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Road, Suite 700  
Schaumburg, IL 60195

Dear Mr. Moutvic :

Please refer to your New Drug Application (NDA) dated January 06, 2012, received January 09, 2012, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zoledronic Acid Injection, 4 mg per 100 mL.

We acknowledge receipt of your amendments dated February 08, 2012; March 05 and 30, 2012; April 16, 2012; May 29, 2012, June 27, 2012; July 19, 2012(2); September 06, 2012(3); September 20, 2012; October 05, 10, 15, 17, and 24, 2012.

This NDA provides for the use of Zoledronic Acid Injection, 4 mg per 100 mL for the treatment of:

- Hypercalcemia of malignancy
- Patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert, overwrap, carton and immediate container labels). This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

Please note that your submitted data does not support a requested (b) (4) of shelf-life but it does support a 12-month expiration dating period. When you submit your amendment prior to the expiration of the patent or exclusivity as described below, please either provide additional stability data to support your requested (b) (4) shelf life or accept a 12-month expiry.

The listed drug upon which your application relies is subject to a period of patent and/or exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1.) expiration of the patent and/or exclusivity protection or 2.) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as “**REQUEST FOR FINAL APPROVAL**”. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and Risk Evaluation and Mitigation Strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

### **PROPRIETARY NAME**

If you intend to have 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 a request for a proposed proprietary name review. See the guidance for industry titled, “Contents of a Complete Submission for the Evaluation of Proprietary Names”, at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.

### **METHODS VALIDATION**

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

If you have any questions, call Kim J. Robertson, Regulatory Project Manager, at (301) 796-1441.

Sincerely,

*{See appended electronic signature page}*

Amna Ibrahim, M.D.  
Deputy Director  
Division of Oncology Products 1  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling  
Overwrap  
Carton and Container 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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AMNA IBRAHIM  
11/09/2012