DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-570/S-004

SUPPLEMENT APPROVAL

EUSA Pharma (USA), Inc.
Attention: Margaret P. Filipiak
Director, Regulatory Affairs
650 College Road East, Suite 3100
Princeton, NJ 08540

Dear Ms. Filipiak:

Please refer to your supplemental new drug application dated April 29, 2008, received April 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Quadramet® (samarium 153 lexidronam) Injection.

We acknowledge receipt of your submission dated November 12, 2008, which constituted a complete response to our October 31, 2008 action letter.

This "Changes Being Effected in 30-days" supplemental new drug application provides for extending the expiration period from eight (8) hours to 56 hours after the time of calibration or 8 hours after thawing, whichever is earlier.

We completed our review of this supplemental new drug application, as amended, and it is approved.

We note your May 13, 2009, commitment to revision the package insert with the following revisions as noted in the April 28, 1999, action letter:

- There is a spelling error in the WARNING Section. It should read "Quadramet causes bone marrow **suppression**…" instead of "Quadramet causes bone marrow **supression**…".
- In the PHARMACODYNAMICS Section, first sentence, change "**average range**" to "**maximum range**" and change "**3.1**" to "**3.0**"

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert submitted November 12, 2008, except with the revisions listed above. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-570/S-004**."

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Tu-Van Lambert, Regulatory Health Project Manager, at (301) 796-4246.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel

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