**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 16, 2019

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Sent via email to: maladdin@citizen.org

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration is requesting that the FDA provide a boxed warning to the product labeling of Prolia describing the risk of vertebral fractures upon drug discontinuation was received by this office on 04/16/2019.

It was assigned docket number FDA-2019-P-1818. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby

Digitally signed by Dynna Bigby
Date: 2019.04.17 10:24:17 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
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