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Dr Eric Abadie
European Medicines Agency
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London E14 4HB
United Kingdom

Cc: Dr Irene Papadouli
EMA

15 NOVEMBER 2007

RE: Withdrawal of ZOMETA (zoledronic acid)
Type II variation EMA/H/C/336/II/021

Dear Dr Abadie

I would like to inform you that Novartis Europharm Limited has taken the decision to withdraw the application for the extension of the ZOMETA marketing authorisation to include the indication "prevention of fracture and bone loss in postmenopausal women with early-stage breast cancer (EBC) treated with aromatase inhibitors (AIs)"

The withdrawal is based on the following reason:

The CHMP considers that the data provided do not allow them to conclude with a recommendation for approval of this type II variation application.

This decision will not have consequences for patients enrolled in the clinical trials.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for such a letter to be published on the EMA website.

Yours sincerely,

On behalf of Novartis Europharm Limited