

Patent Attorney  
Oncology

Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover NJ 07936-1080



Tel (862) 778-7852  
Fax (973) 781-8064  
Internet: oona.jackson  
@novartis.com

May 4, 2005

# F A X

3 Pages

Dockets Management Branch  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

RE: 02E-0020  
Zometa

To Whom It May Concern:

The Federal Register: Volume 68, Number 40 dated February 28, 2003 mistakenly published the effective date for Zometa® as December 12, 1993. The effective date for Zometa® is September 12, 1993, which is 30 days from the date of receipt of the IND, please refer to the attached FDA letter stating that the date of receipt of the IND is August 13.

It is my understanding, based on the conversations I have had with Claudia Grillo that the FDA will publish the correct effective date in the Federal Register. Please note the effective date will help to establish the patent term extension for U.S. Patent No. 4,939,130.

If you have any questions, please do not hesitate to contact me at (862) 778-7852.

Regards,

  
Oona A. Jackson, Esq.

Attachment

02E-0020

LET 5



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

93-147

8-1

Food and Drug Administration  
Rockville MD 20857

IND 43,240

Date August 19, 1993

Ciba-Geigy Corporation  
Attention: Ronald M. Califre  
556 Morris Avenue  
Summit, New Jersey 07901

Dear Sir or Madam:

We acknowledge receipt of your Investigational New Drug Application (IND) submitted pursuant to Section 505(i) of the Federal Food, Drug, and Cosmetic Act. Please note the following identifying data:

IND Number Assigned: 43,240

Sponsor: Ciba-Geigy Corporation

Name of Drug: CGP 42446

Date of Submission: August 12, 1993

Date of Receipt: August 13, 1993

Studies in humans may not be initiated until 30 days after the date of receipt shown above. If, within the 30-day waiting period, we identify deficiencies in the IND that require correction before human studies begin or that require restriction of human studies until correction, we will notify you immediately that the study may not be initiated ("clinical hold") or that certain restrictions must be placed on it. In the event of such notification, you must continue to withhold, or to restrict, such studies until you have submitted material to correct the deficiencies, and we have notified you that the material you submitted is satisfactory.

It has not been our policy to object to a sponsor, upon receipt of this acknowledgement letter, either obtaining supplies of the investigational drug or shipping it to investigators listed in the IND. However, if drug is shipped to investigators, they should be reminded that studies may not begin under the IND until 30 days after the IND receipt date or later if the IND is placed on clinical hold.

**RECEIVED****SEP 15 1993****DRA FILES**

IND 43,240

Page 2

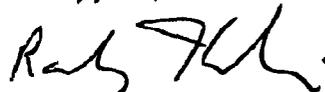
You are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the regulations implementing that Act (Title 21 of the Code of Federal Regulations). Those responsibilities include reporting any adverse experience associated with use of the drug that is both serious and unexpected to the FDA as soon as possible and in no event later than 10 working days after initial receipt of the information and reporting any unexpected fatal or life-threatening experience to the FDA by telephone no later than 3 working days after receipt of the information (21 CFR 312.32), and submission of annual progress reports (21 CFR 312.33).

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, and addressed as follows:

Food and Drug Administration  
Center for Drug Evaluation and Research (HFD-510)  
Attention: Document Control Room  
5600 Fishers Lane  
Rockville, Maryland 20857

Should you have any questions concerning this IND, please contact **Randy Hedin.**

Sincerely yours,



Consumer Safety Officer  
Division of Metabolism and Endocrine  
Drug Products  
Office of Drug Evaluation  
Center for Drug Evaluation and Research

cc: Original IND - pink  
HFD-510 - yellow  
HFD-510/CSO - green

IND ACKNOWLEDGEMENT