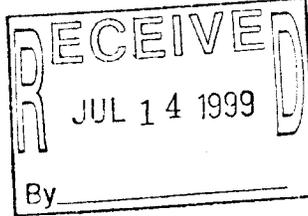


DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

IND 58,554



JUL 12 1999

Novartis Pharmaceuticals Corporation
 Attention: Ms. Eileen A. Ryan
 59 Route 10
 East Hanover, New Jersey 07936-1080

Dear Ms. Ryan:

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

IND Number Assigned: 58,554

Sponsor: Novartis Pharmaceuticals Corporation

Name of Drug: ICL 670 Dispersible Tablets

Date of Submission: June 30, 1999

Date of Receipt: July 1, 1999

Studies in humans may not be initiated until 30 days after the date of receipt shown above. If, on or before July 31, 1999, we identify deficiencies in the IND that require correction before human studies begin or that require restriction of human studies, we will notify you immediately that (1) clinical studies may not be initiated under this IND ("clinical hold") or that (2) certain restrictions apply to clinical studies under this IND ("partial clinical hold"). In the event of such notification, you must not initiate or you must restrict such studies until you have submitted information to correct the deficiencies, and we have notified you that the information 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 the 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.

As sponsor of this IND, you are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and the implementing regulations (Title 21 of the Code of Federal Regulations). Those responsibilities include (1) reporting any unexpected fatal or life-threatening adverse experience associated with use of the drug by telephone or fax no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)]; (2) reporting any adverse experience associated with use of the drug that is both serious and unexpected in writing no later than 15 calendar days after initial receipt of the information [21 CFR 312.32(c)(1)]; and (3) submitting annual progress reports [21 CFR 312.33].

Please forward all future communications concerning this IND in triplicate, identified by the above IND number, to the following address:

U.S. Postal Service/Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: Division Document Room, 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, contact me at (301) 827-7310.

Sincerely yours,



Alice Kacuba, RN, MSN
Regulatory Health Project Manager
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research



Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 973 781 7500
Fax 973 781 6325

June 30, 1999

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
12229 Wilkins Avenue
Rockville, Maryland 20852

ICL 670 Dispersible Tablets

INVESTIGATIONAL NEW DRUG APPLICATION

Serial No. 000

Dear Sir or Madam:

In accordance with 21 CFR §312.23, attached is our investigational New Drug Application (FDA Form 1571) and supporting documents for the following investigational compound:

ICL 670 Dispersible Tablets

Indication: Iron Chelation

I wish to bring to your attention that Section 6 includes two protocols each with a question directed to the FDA reviewer (s). The protocols are:

- 1) Protocol CICL 670 0103 entitled "Open metabolic iron balance study with three single oral doses of ICL670A in patients with transfusion-dependent β -thalassemia" and Amendment #1 to CICL 670 0103.

It is our intention to initiate this protocol after the 30 day review clock expires. Also included is Amendment No 1 which provides for the inclusion of adolescents over the age of 14 years in Protocol CICL 670 0103. A justification for this amendment is also included in Section VI and a question to the FDA relative to Amendment No: 1 is provided.

- 2) Draft protocol CICL670 0102: entitled "Double-blind, placebo-controlled time-lagged, parallel group study to evaluate the safety and tolerability of ascending multiple oral doses of ICL670A administered to patients with transfusion-dependent β -thalassemia".

The sponsor has provided this protocol for FDA comment. This protocol represents the first multi-dose trial and is expected to begin in September. Provided with this protocol is a question for the FDA reviewer relative to the dose selection. Also because this study is a multi dose study an ophthalmic assessment is included on a finding of cataracts in a repeat dose rat toxicology study.

We respectfully request your review of Protocol CICL 0103 and Amendment No. 1 within the 30 day review period.

A response to our question on Protocol CICL 0102 would be appreciated by August so the trial may initiate in September.

This IND application and all subsequent amendments thereto are confidential and their contents are not to be disclosed without the express written consent of Novartis Pharmaceuticals Corporation.

If you have any questions or comments, please contact me at (973) 781-7661.

Sincerely,



Eileen A Ryan
Associate Director
Drug Regulatory Affairs

/cs
Attachments
Submitted in triplicate

990630cs.doc