HFD-104
D. Murphy
Rec'd 5/26/00

NDA 20-929

MAY 22 2000

AstraZeneca
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Attention: Eric Couture, Ph.D.
Director, Regulatory Affairs

Dear Dr. Couture:

Reference is made to the FDA's December 14, 1998, Written Request for pediatric studies for budesonide, and to the FDA's December 22, 1999, amended Written Request.

Reference is also made to your submission dated February 28, 2000, to IND 44,535, which contains a proposed draft protocol and a meeting request to obtain clarification on the FDA's Written Request, and to the subsequent teleconference between representatives of AstraZeneca and the Division of Pulmonary and Allergy Drug Products on April 14, 2000.

As a result of the April 14, 2000, teleconference we are amending the below listed sections of the Written Request. All other terms stated in our Written Request issued on December 14, 1998, and the amendment issued on December 22, 1999, remain the same.

Entry criteria:

Study 1: Children between the ages of 6 months and one year with asthma or asthma-like signs and symptoms who are likely to benefit from inhaled corticosteroids. The subjects should not have received systemic corticosteroids for at least 2 months and should have a normal baseline test of HPA-axis function, either cosyntropin stimulation test or another sensitive test of adrenal function such as timed or overnight urinary cortisol. Subjects who have received inhaled corticosteroids likewise may be recruited; however, they must undergo a minimum of a 2-week "washout" prior to entry into the trial. They also must have a normal baseline test of HPA-axis function, as specified above.

Timeframe:

Studies 1 & 2: Full study reports must be submitted to the Agency by July 31, 2002.

Reports of the studies that meet the terms of the Written Request dated December 14, 1998, as amended on December 22, 1999, and by this letter must be submitted to the Agency on or before July 31, 2002, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Please submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, "PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC EXCLUSIVITY STUDY" in large font, bolded type at the beginning of the cover letter of the submission. Please notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, "PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES" in large font, bolded type at the beginning of the cover letter of the submission.

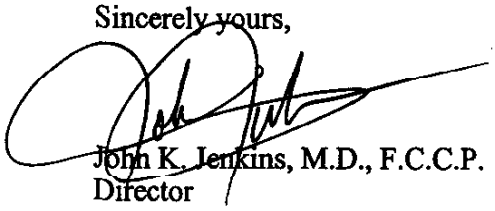
Reports of the studies should be submitted as a supplement to your approved NDA, new drug application, or an amendment to your pending application with the proposed labeling changes you believe would be warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED" in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. Please also send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked "PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES" in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed upon by the Agency.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, contact Mrs. Gretchen Trout, Regulatory Project Manager, at 301-827-1058.

Sincerely yours,



John K. Jenkins, M.D., F.C.C.P.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Archival NDAs 20-746 and 20-929
Archival INDs 21,632 and 44,535
HFD-570/division files
HFD-570/Trout
HFD-570/Purucker
HFD-570/Anthracite
HFD-570/Elashoff
HFD-570/Wilson
HFD-570/Chowdhury
HFD-570/Meyer
HFD-102/Jenkins
HFD-600/Office of Generic Drugs
HFD-2/M.Lumpkin
HFD-104/Peds/D.Murphy
HFD-104/Peds/T.Crescenzi

Drafted by: GST and MP/April 26, 2000
Initialed by: Elashoff/5-4-00
Wilson/5-4-00
Purucker/5-12-00
Meyer/5-12-00

Final: Trout/5-15-00
filename: n:\staff\troutg\20929awr

REVISED PEDIATRIC WRITTEN REQUEST LETTER
INFORMATION REQUEST (IR)