CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75313

BIOEQUIVALENCY REVIEW(S)

Ipratropium Bromide Inhalation Solution
0.02% w/v
ANDA # 75-313
Reviewer: Hoainhon Nguyen

Zenith Goldline*
Northvale, NJ
Submission Date:
March 9, 1998
*Agent for Steripak Ltd., UK
May 12 &13, 1998
(Fax Telephone Amendments)

Review of a Waiver Request

The firm has requested a waiver from in vivo bioavailability requirements for its Ipratropium Bromide Inhalation Solution, 0.02% w/v, in accordance with 21 CFR 320.22 (b) (3).

Comments:

1. The test product is an inhalation solution.

2. The formulation of the test product is identical, quanlitatively and quantitatively, to that of the currently approved Atrovent[R] Inhalation Solution, 0.02% w/v, manufactured by Boehringer Ingelheim, as shown below:

Ingredients	Test Formula	Atrovent's Formula
Ipratropium Bromide		
Sodium Chloride		
Water		
Diluted Hydrochloric Acid	as needed for pH adjustment	as needed for pH adjustment
Total	mL (100%)	mL (100%)

Recommendations:

The Division of Bioequivalence agrees that the information submitted by Zenith Goldline/Steripak Ltd. demonstrates that its Ipratropium Bromide Inhalation Solution, 0.02% w/v, fall under 21 CFR 320.22 (b) (3) of the Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of in vivo bioavailability study be granted. The test product, Ipratropium Bromide Inhalation Solution, 0.02% w/v, is deemed bioequivalent to the currently approved Atrovent[R] Inhalation Solution, 0.02% w/v, (base)/mL, manufactured by Boehringer Ingelheim.

/S/

Hoainhon Nguyen
Division of Bioequivalence
Review Branch I

RD INITIALED YHUANG
FT INITIALED YHUANG /S/ 5/14/98

Concur: /S/ Date: 5/14/98

Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence

cc: ANDA # 75-313 (original, duplicate), HFD-652(Huang, Nguyen), Drug File, Division File

Attachments: None

BIOEQUIVALENCY COMMENTS

ANDA: 75-313

APPLICANT: Zenith Goldline
Agent for Steripak Ltd., UK

DRUG PRODUCT: Ipratropium Bromide Inhalation Solution, 0.02% w/v

The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,

/S/

Dale P. Conner, Pharm. D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research