CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 74-830

CORRESPONDENCE

Pharmaceutical Division 8500 Hidden River Parkway Tampa FL 33637 813 975 7700 Fax 813 975 7770

BAUSCH & LOMB
Healthcare and Optics Worldwide

December 31, 1995

Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: Desmopressin Acetate Nasal Solution, 0.01%
ANDA Submission

Dear Sir or Madam:

In accordance with the provisions set forth in 21 CFR 314.94, we are submitting this abbreviated new drug application, in duplicate, for Desmopressin Acetate Nasal Solution, 0.01%. This product is indicated for the management of primary nocturnal enuresis. This product is also indicated as antidiuretic replacement therapy in the management of central cranial diabetes insipidus and for the management of the temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.

An analytical methods validation package, which includes three (3) additional copies of non-compendial assay procedures and their corresponding validation studies, is provided under separate cover.

Standard operating procedures (SOPs) are provided throughout this application as an aid in the review process. Revisions may be made to these SOPs after appropriate in-house review and approval. Changes which influence the manufacture of Desmopressin Acetate Nasal Solution, 0.01% will be reported to the agency as per the criteria established under 21 CFR 314.70.

In accordance with 21 CFR 314.94 (d)(5), we certify that a true field copy has been sent to our FDA district office in Orlando, Florida. The information contained in this submission is confidential and as such should be handled in accordance with the provisions established in 21 CFR 314.430.

If you have any questions or comments concerning this application, please contact me at the above address or at (813) 975-7775.

Sincerely,

Peter Stoelzle
Director
Regulatory Affairs

Enclosures

Pharmaceutical Division | 8500 Hidden River Parkway Tampa FL 33637 | 813 975 7700 Fax 813 975 7770

November 7, 1996

BAUSCH & LOMB
Healthcare and Optics Worldwide

HFC

AC

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II, Room 150
7500 Standish Place
Rockville, MD 20855-2773

RE: ANDA 74-830
Desmopressin Acetate Nasal Solution, 0.01%
Major Amendment Correspondence

Dear Sir or Madam:

The purpose of this correspondence is to respond to the agency's August 21, 1996 "not approvable" letter for the above referenced application.

To facilitate your review, each of the questions and our corresponding response is provided as an attachment to this amendment. The question numbers correspond to those in the Agency's August 21, 1996 "not approvable" letter. Necessary supportive documentation is also provided for each response.

In accordance with 21 CFR 314.96 (b), we certify that a true copy of the information contained in this amendment has been forwarded to FDA's Orlando District Office.

We believe that this correspondence provides a thorough response to the questions raised in the agency's August 21, 1996 letter. As such, we hope that a rapid review and subsequent product approval will be forthcoming. If you have any questions regarding this correspondence, please contact me at the above address or by telephone at (813) 975-7775.

Sincerely,

Joseph B. Hawkins
Sr. Specialist,
Regulatory Affairs

enclosure

Pharmaceutical Division | 8500 Hidden River Parkway Tampa FL 33637 | 813 975 7700 Fax 813 975 7770

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BAUSCH & LOMB
Healthcare and Optics Worldwide

February 28, 1997

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room
Metro Park North II, Room 150
7500 Standish Place
Rockville, MD 20855-2773

NDA ORIG AMENDMENT
N/AC

Re: ANDA 74-830
Desmopressin Acetate Nasal Solution, 0.01%
Gratuitous Amendment

Dear Sir or Madam:

The purpose of this correspondence is to amend our submission of November 7, 1996 which responded to the Agency's August 21, 1996 "not approvable" letter for the above referenced application.

To facilitate the revision of our November 7, 1996 submission, it is necessary to replace sections A.1., A.11., and A.15. of the November 7th submission with the sections contained in this amendment.

Each of these questions and our corresponding response is provided as an attachment to this amendment. The question numbers correspond to those in the Agency's August 21, 1996 "not approvable" letter. Necessary supportive documentation is also provided for each response.

In accordance with 21 CFR 314.96 (b), we certify that a true copy of the information contained in this amendment has been forwarded to FDA's Orlando District Office.

We believe that this correspondence provides a more thorough response to the three questions raised in the agency's August 21, 1996 letter. As such, we hope that a rapid review and subsequent product approval will be forthcoming. If you have any questions regarding this correspondence, please contact me at the above address or by telephone at (813) 975-7775 or by fax at 813-975-7757.

Sincerely,

Joseph B. Hawk

Joseph B. Hawkins
Sr. Specialist,
Regulatory Affairs

enclosure

RECEIVED
MAR 03 1997
GENERIC DRUGS