

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 20545**

**CHEMISTRY REVIEW(S)**



RELATED DOCUMENTS (if applicable): None

CONSULTS: None

REMARKS/COMMENTS:

Procainamide BID is a reformulation of an approved and marketed class IA antiarrhythmic agent Procainamide SR tablets that are in market since 1980. This new tablet controlled sustained release formulation permits twice-daily administration, enhancing compliance and minimizing the risk of missed doses.

The drug substance and drug product are manufactured by the Parke-Davis company.

EER was requested on 02/01/95. **Acceptable 12/01/95.**

Methods validation for drug product was requested on 03/20/95 from one philadelphia laboratory and results are reported.

CONCLUSIONS & RECOMMENDATIONS:

The methods are acceptable for the regulatory purposes.  
Application is approvable

cc:  
Orig. NDA  
HFD-110/Division File  
HFD-110/JAdvani/12/13/95  
HFD-110/CSO  
District

2 - **/S/**

R/D Init by: RWolters/

JV Advani, Review Chemist  
filename:N20-545V

*JV Advani*  
*12/14/95*



RELATED DOCUMENTS (if applicable): None

CONSULTS: None

REMARKS/COMMENTS:

Procainamide BID is a reformulation of an approved and marketed class IA antiarrhythmic agent Procainamide SR tablets that are in market since 1980. This new tablet controlled sustained release formulation permits twice-daily administration, enhancing compliance and minimizing the risk of missed doses.

**This amendment provides a update on NDA with corrections and revisions in batch records.**

CONCLUSIONS & RECOMMENDATIONS:

Firm has amended this NDA to update batch records with minor revisions that are to clarify to the manufacturing process documentation, to be used during the manufacture of the pre-validation batch for procanbid. The chemistry and manufacturing part is satisfactory .

cc:  
Orig. NDA  
HFD-110/Division File  
HFD-110/JAdvani/09/05/95  
HFD-110/CSO  
District

✓  
/S/

R/D Init by: RWolters/

JV Advani, Review Chemist  
filename: N20-545IV

✓ /S/  
UJ 9/8/96



RELATED DOCUMENTS (if applicable): None

CONSULTS: None

REMARKS/COMMENTS:

Procainamide BID is a reformulation of an approved and marketed class IA antiarrhythmic agent Procainamide SR tablets that are in market since 1980. This new tablet controlled sustained release formulation permits twice-daily administration, enhancing compliance and minimizing the risk of missed doses.

This amendment provides a response to our deficiencies conveyed to the firm by telephone on 6/27/95 related to my review #2, and update on NDA with corrections and revisions.

CONCLUSIONS & RECOMMENDATIONS:

Firm has amended this NDA that include minor modifications to the manufacturing process and in-process controls which will be used during the manufacture of the pre-validation batch for procainid. The chemistry and manufacturing part is satisfactory.

cc:

Orig. NDA

HFD-110/Division File

HFD-110/JAdvani/07/19/95

HFD-110/CSO

District

R/D Init by: RWolters/

*IS!*  
\_\_\_\_\_  
JV Advani, Review Chemist  
filename: N20-545III

*Wolters  
7/20/95*



RELATED DOCUMENTS (if applicable): None

CONSULTS: None

REMARKS/COMMENTS:

Procainamide BID is a reformulation of an approved and marketed class IA antiarrhythmic agent Procainamide SR tablets that are in market since 1980. This new tablet controlled sustained release formulation permits twice-daily administration, enhancing compliance and minimizing the risk of missed doses.

This amendment provides a response to our deficiencies letter of 3/15/95 related to my review #1, and update on NDA with corrections and revisions, and further information, on stability data, as result of our meeting with the representatives of the firm on 4/5/95. Copies of the minutes are provided in this submission. The firm has addressed the questions raised by us, in this submission

CONCLUSIONS & RECOMMENDATIONS:

I received a call from Mr Alexander J. Brankiewicz of Parke- Davis on 6/27/95. Firm intends to amend this NDA that will include minor modifications to the manufacturing process and in-process controls which will be used during the manufacture of the pre-validation batch for-procanbid. During that conversation I mentioned to him few deficiencies of this amendment outlined under this review, and firm will address these also in their forth-coming submission.

CC:  
Orig. NDA  
HFD-110/Division File  
HFD-110/JAdvani/06/29/95  
HFD-110/CSO  
District

/S/

R/D Init by: RWalters/

JV Advani Review Chemist  
filename: N20-545II

*Approved*  
*7/7/95*



RELATED DOCUMENTS (if applicable): None

CONSULTS: None

REMARKS/COMMENTS:

Procainamide BID is a reformulation of an approved and marketed class IA antiarrhythmic agent Procainamide SR tablets that are in market since 1980. This new tablet controlled sustained release formulation permits twice-daily administration, enhancing compliance and minimizing the risk of missed doses.

This is a 505(b)(2) application as procainamide hydrochloride preparations have been generally recognised as safe and effective (FR DESI 6320 of 9/72) for use in the treatment of ventricular arrhythmias.

The trademark was found to be acceptable by the Labelling and Nomenclature committee.

We had two Pre-NDA meetings on CMC sections, the copies of the minutes are provided in this submission. The firm has addressed the questions raised by us, in their NDA submission

CONCLUSIONS & RECOMMENDATIONS:

In my telephone conversations on 01/30/95, with Mr. Alex Brankiewicz of Parke Davis, I ask the firm to update their stability data according to the ICH latest guidelines. I wanted to know their production batches that were manufactured at Vega Baja, Puerto Rico plant and further I ask the firm to provide the additional information on the exact responsibilities of Paco for the blister packaging operations. Firm has provided the written answers of my request in their letter of 2/13/95. All this has been discussed in my review, and additional deficiencies noted in the review, have been summarized in the draft of the controls portion of the letter to the applicant.

cc:  
Orig. NDA  
HFD-110/Division File  
HFD-110/JAdvani/02/28/95  
HFD-110/CSO  
District

/S/

R/D Init by: RWolters/

JV Advani, Review Chemist  
filename: N20-545

*Handwritten signature and date: RWolters 5/14/95*