CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

63065/S14, S15

ADMINISTRATIVE DOCUMENTS

REVIEW OF PROFESSIONAL LABELING

SUPPLEMENTAL AMENDMENT

FPL

ANDA #: 63-065/S-015

NAME OF FIRM: Danbury Pharmacal, Inc.

NAME OF DRUG: Minocycline Hydrochloride Capsules USP, 75 mg

DATE OF SUBMISSION: April 5, 1999

COMMENTS:

1. CONTAINER (100s and 500s)

   Satisfactory in final print.

2. INSERT

   Satisfactory in final print.

RECOMMENDATIONS:

Supplement 15 is satisfactory for approval from a labeling point of view.

FOR THE RECORD:

1. Labeling Model:

   Review based on the labeling of Minocin®; Revised August 1995; Approved 8/8/95.

2. On May 27, 1993 a letter was issued to firm to inform them that it was determined that the proprietary name being used by Medicis was objectionable due to its similarity to (Dicloxacillin). The firm has submitted progress reports regarding the use of the proprietary name that showed an absence of any reports on dispensing issues, therefore the name will not be forwarded to the CDER Labeling and Nomenclature committee.

3. From previous review/reviewer:

a. This is a combined chemistry and labeling supplement for the addition of a new strength (75 mg). This dose seems only appropriate for the pediatric dosing section.

b. A citizens petition was approved May 26, 1998 for the additional strength.

cc: ANDA 63-065/S-015
Division File
HFD-613/JWhite/CHoppes JWhite PhD 5/28/99

Review

/S/ 5/27/98

REVIEW OF PROFESSIONAL LABELING # 1

SUPPLEMENT

FPL

DATE OF REVIEW: September 14, 1998

ANDA #: 63-065/S-015

NAME OF FIRM: Danbury Pharmacal, Inc.

NAME OF DRUG: Minocycline Hydrochloride Capsules USP, 75 mg

DATE OF SUBMISSION: July 31, 1998

COMMENTS:

1. CONTAINER (100s and 500s)

   a. Increase the prominence of the strength on the container of 100.

   b. Only six copies of the container were included with this submission.

2. INSERT

   Satisfactory in final print. However, only six copies of the insert were included with this submission.

RECOMMENDATIONS:

1. Inform the firm of the above comments.

2. Request the firm submit six more copies of final printed labels and labeling.

FOR THE RECORD:

1. Review based on the labeling of Minocin®; Revised August 1995; Approved 8/8/95.

2. This is a combined chemistry and labeling supplement for the addition of a new strength (75 mg). This dose seems only appropriate for the pediatric dosing section.

3. A citizens petition was approved May 26, 1998 for the additional strength.

cc: ANDA 63-065/S-015
Division File
HFD-613/CHolquist/JGrace

Review

10/1/98 10/6/98