DIVISION OF ANTIVIRAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-977  CHEMISTRY REVIEW #: 1  REVIEW DATE: 12-4-98

SUBMISSION TYPE  DOCUMENT DATE  CDER DATE  ASSIGNED DATE
CMC Pre-submission  3-27-98  3-30-98  4-13-98
Original  6-24-98  6-29-98
Amendment BC  7-10-98  7-13-98  7-20-98
Amendment BC  8-28-98  8-31-98  9-16-98
Amendment BC  10-30-98  11-2-98  11-2-98
Amendment BC  11-10-98  11-12-98  11-12-98
Amendment BL  11-12-98  11-13-98  11-13-98
Amendment BL  12-3-98  12-4-98  12-4-98

NAME & ADDRESS OF APPLICANT:
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

DRUG NAME:
Proprietary:
Nonproprietary: ZIAGEN™
Code Name/#:
Abacavir Sulfate (USAN, BAN, and INN)
CAS Registry Number:
1592U89 Heminisulfate
188062-50-2

PHARMACOLOGICAL CATEGORY:
Antiviral
INDICATION:
Anti-HIV

DOSAGE FORM:
Film coated tablets
STRENGTH:
300 mg of abacavir as abacavir sulfate per tablet.

ROUTE OF ADMINISTRATION:
Oral

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT.:

Chemical Name: (1S, cis)-4-[2-Amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1)

IUPAC: [4R-(2-Amino-6-cyclopropylamino-purin-9-yl)-cyclopent-2-en-1S-yl]-methanol sulfate (2:1)

Structural Formula:
Molecular Formula: \((\text{C}_{14}\text{H}_{18}\text{N}_{6}\text{O})_2 \cdot \text{H}_2\text{SO}_4\)

Molecular Weight: 670.76

Chirality/Stereochemistry: abacavir sulfate is a single enantiomer with 1S, 4R configuration.

**SUPPORTING DOCUMENTS:**

**CONCLUSIONS & RECOMMENDATIONS:**

From the CMC stand point the NDA 20-977 for Ziagen™ (abacavir sulfate) tablets is approved. An expiration dating period of 18 months is recommended for abacavir sulfate tablets that are packaged in bottles of 60 and 180 counts or in unit dose PVC blisters and, stored at controlled room temperature of 20° to 25°C (68° to 77° F) (see USP). In the NDA Action Letter a statement should be included indicating that the analytical methods validation by the FDA District Laboratories is pending.

Rao V. Kambhampati, Ph.D.
Senior Regulatory Review Scientist

Concurrence:
HFD-530/Chem. TL/SMiller
ZIAGEN  

**abacavir sulfate**

The Committee noted sound-alike/look-alike conflicts with the following marketed products: ZIAC, OGEN and Z-GEN. The committee felt there was a low potential for mix-up with these products since they have different strengths, indications and marketing classes. There were no misleading aspects found.

The Committee has no reason to find the proposed proprietary name unacceptable.

/S/

[Signature]

CDER Labeling and Nomenclature Committee

**APPEARS THIS WAY ON ORIGINAL.**
CONSULT #943

LNC TRADEMARK REVIEW

TO: HFD-530

ATTN: Dan Boring  Rao Khambampiti

PROPOSED NAME(S): ZIAGEN

ESTABLISHED NAME: abacavir sulfate tablets

COMMITTEE'S COMMENTS:

A review revealed no names which sound like or look like the proposed name.

The Committee has no reason to find the proposed name unacceptable.

Dan Boring, Ph.D., Chairman
Labeling and Nomenclature Committee