CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-543

STATISTICAL REVIEW(S)

Memorandum for the Record
Division of Biometrics II

NDA #: 21-543

Applicant: Columbia Labs.

Trade/Generic Name: Striant™ (testosterone mucoadhesive buccal tablet)

Indication: Testosterone replacement therapy

Date of Submission: Aug 19, 2002

Filing Mtg: Sep 26, 2002

User Fee Goal Date: Jun 19, 2003

Project Manager: Ms. Deguia (HFD 580)

Medical Reviewer: Dr. Handelsman (HFD 580)

Statistical Reviewer: Mike Welch (HFD 715)

Comments:

Striant™ (testosterone mucoadhesive buccal tablet) is a controlled and sustained release buccal bioadhesive product. Each tablet contains 30 mg of the primary androgen testosterone and bioadhesive excipients. The product is applied to the gum tissue above the incisors and slowly releases testosterone for absorption across the oral mucosa as the tablet gradually hydrates.

Striant™ was evaluated in a multicenter, open-label, single arm, phase 3 trial in 82 hypogonadal men .The buccal bioadhesives were administered twice daily for 12 weeks. Of these 82 patients who completed the trial and had sufficient data for full analysis, 86.6% had mean serum testosterone values within the desired physiologic range. Study results are presented as descriptive statistics only. A separate statistical review is not necessary.

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/s/

Mike Welch
5/23/03 01:24:38 PM
BIOMETRICS

Screening of New NDA for Statistical Filing
Division of Biometrics II

NDA #: 21-543

Applicant: Columbia Labs.

Trade/Generic Name: Testosterone Buccal Adhesive

Indication: Testosterone replacement therapy in men

Date of Submission: Aug 19, 2002

Filing Mtg: Sep 26, 2002

User Fee Goal Date: Jun 19, 2003

Project Manager: Deguia

Medical Reviewer: Handelsman

Comments: This NDA is fileable from a statistical perspective. A single principal study (COL-1621-05) supports efficacy. This is an open label, uncontrolled study. Efficacy is based on percentage of patients who achieve pre-defined average and minimum testosterone concentration levels at end of study. Study results are descriptive only. A separate statistical review will not be needed. A short review memo should suffice for verification of sponsor's results.

Checklist for Fileability	Remarks (NA if not applicable)
Index sufficient to locate study reports, analyses, protocols, ISE, ISS, etc.	OK
Original protocols & subsequent amendments submitted	OK
Study designs utilized appropriate for the indications requested	OK
Endpoints and methods of analysis spelled out in the protocols	OK
Interim analyses (if present) planned in the protocol and appropriate adjustments in significance level made	NA
Appropriate references included for novel statistical methodology (if present)	NA
Data and reports from primary studies submitted to EDR according to Guidances	Access to EDR data OK
Safety and efficacy for gender, racial, geriatric, and/or other necessary subgroups investigated	OK

Reviewer: M. Welch

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/s/

Mike Welch
9/26/02 02:47:21 PM
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