CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208612Orig1s000

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Science
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number:	208612
Drug Name:	(b) (4) (levonorgestrel 0.1-mg/ethinyl estradiol 0.02-mg tablets)
Indication:	Prevention of Pregnancy
Applicant:	Neuvosyn Laboratories, LLC
Date(s):	Submission Date: 3/14/2017 PDUFA Due Date: 1/14/2018
Review Priority:	Standard
Biometrics Division:	Division of Biometrics III
Statistical Reviewer:	Kate Li Dwyer, Ph.D.
Concurring Reviewers:	Mahboob Sobhan, Ph.D.
Medical Division:	Division of Bone, Reproductive and Urologic Drug Products
Clinical Team:	Abby Anderson, M.D., Medical Reviewer Catherine Sewell, M.D., Acting Team Leader
Project Manager:	Jennifer Dao

Keywords: NDA review, clinical studies

BACKGROUND

Neuvosyn has developed a fixed-dose combination of an oral contraceptive containing levonorgestrel 0.1-mg and ethinyl estradiol 0.02-mg tablets copackaged with 7 nonhormonal (placebo) iron tablets each containing (b) (4) Ferrochel® (equivalent to 10 mg elemental iron). The iron placebo tablets are present to facilitate ease of drug administration in a 28-day regimen and do not serve any therapeutic purpose.

Neuvosyn's proposed product is indicated to prevent pregnancy in women who chose an oral contraceptive as their method of contraception. The dosing regimen consists of continuous dosing for 21 consecutive days followed by 7 days on placebo tablets.

Neuvosyn has not conducted any clinical trials in support of this proposed product. To support the efficacy of their levonorgestrel 0.1-mg/ethinyl estradiol 0.02-mg tablet, Neuvosyn relies on the Agency's previous findings of safety and efficacy for Alesse Tablets (NDA 020683). Neuvosyn has obtained a right of reference from Novast to ANDA 090721 to support approval.

CONCLUSION

There is no new efficacy data submitted in support of this NDA. Therefore, no statistical review is necessary.

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/s/

KATE L DWYER
08/31/2017

MAHBOOB SOBHAN
09/06/2017