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APPLICATION NUMBER:
022501Orig1s000

OTHER REVIEW(S)

NDA 022501 (Lo Loestrin Fe)
Labeling Review

NDA 022501 Labeling Review
Memo to File

The labeling, as submitted by the Sponsor on October 19, 2010, is acceptable to the Division.

Ronald J. Orleans, M.D.
Medical Officer

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/s/

RONALD J ORLEANS
10/21/2010

LISA M SOULE
10/21/2010

SEALD LABELING: FINAL SIGN-OFF REVIEW

APPLICATION NUMBER	NDA 22-501
APPLICANT	Warner Chilcott, Inc.
DRUG NAME	Lo Loestrin Fe (norethindrone acetate and ethinyl estradiol tablets, ethinyl estradiol tablets, and ferrous fumarate tablets)
SUBMISSION DATE	April 20, 2010
PDUFA DATE	October 21, 2010
SEALD REVIEW DATE	October 19, 2010
OND ASSOCIATE DIRECTOR FOR LABELING OR DESIGNEE	Ann Marie Trentacosti for Laurie Burke

This review confirms that the final draft labeling meets the minimum requirements of 21 CFR 201.56 and 201.57 and related CDER labeling policies.

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/s/

ANN M TRENTACOSTI
10/19/2010
Signing for Laurie Burke

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