EXHIBIT 1020

Guidance for Industry

Labeling for Combined Oral Contraceptives

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication of the *Federal Register* notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact Margaret Kober, 301-827-4243.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2004
Labeling

Revision 1

Guidance for Industry

Labeling for Combined Oral Contraceptives

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U.S. Department of Health and Human Services
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I. INTRODUCTION

This guidance describes the recommended labeling for health care providers and patient instructions for use for new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for combined oral contraceptives (OCs) that contain estrogen and progestin. A draft guidance on this topic was issued for comment in June 2000. Many comments were received on the 2000 draft guidance and, as a result, many changes have been made to the guidance. Because of the many changes, we are making the guidance available again in draft to allow for additional public review and input. The references listed at the end of this guidance do not go in the labeling.

[1] This guidance was developed by the Division of Reproductive and Urologic Drug Products in the Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA).

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