Ibis
Reproductive
Health

December 17, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: Docket No. 2007N-0356 in the October 4, 2007 *Federal Register* (Vol 72; No 192)

Thank you for the opportunity to comment on the possible creation of a "behind-the-counter" category of medicines in the United States. We at Ibis Reproductive Health are supportive of strategies to increase access to medications and to reducing barriers to access, particularly barriers that include the requirement for a physician visit or prescription where the available clinical data do not indicate that requiring such costly visits improves health outcomes.

We are concerned, however, about ensuring that any decision to create a "behind-the-counter" category is based on sound evidence and successfully improves access, and does not lead to a circumstance where medicines that could be over-the-counter require unnecessary pharmacist intervention. We believe that research on current "behind-the-counter" strategies in other countries could usefully shed light on where and for what medicines this third category might be useful. We also believe that the FDA would need to develop detailed guidelines, based on the best current evidence, to differentiate between appropriate "behind-the-counter" and "over-the-counter" (OTC) access for different classes of drugs. These guidelines should be based on extensive research about the potential benefits and costs to patients, and reflect how patients can most easily access medicines and use them safely and effectively with the least interference.

Finally, considering oral contraceptives and other hormonal contraceptive methods as an example, we believe that the current FDA structure impedes changes in the labeling which would provide consumers and physicians with the most up-to-date information about provision, safety, effectiveness and non-contraceptive benefits. Oral contraceptives meet all the FDA criteria for OTC access, yet because of disincentives for pharmaceutical companies, there is as yet no major company applying to switch its products to OTC. We would encourage FDA to consider whether its limited resources are best spent creating a new category of medicine, or whether a review of current practice and labeling, encouraging companies to move appropriate products OTC where supported by available data, and including information relevant to physicians and patients might more quickly increase patient access and improve health outcomes.

Sincerely,

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