

Consumer Healthcare Products Association

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Oral Remarks Before the Nonprescription Drugs Advisory Committee On the Matter of Comparative Effectiveness Labeling on OTC Spermicide Products

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CHPA is the 119-year-old trade organization representing producers of quality nonprescription drugs and dietary supplements, including over 200 members across the manufacturing, distributing, supply, research testing, and advertising sectors of the self-care industry. CHPA members produce OTC spermicide products under the brand names Conceptrol and Semicid.

We are here today to address the issue of labeling of OTC spermicide products and plan to submit comments to the OTC docket covering spermicides marketed pursuant to an OTC monograph and to the record of the NDAC deliberations on the vaginal contraceptive sponge.

As background, about two million women use spermicide-containing vaginal contraceptives. OTC spermicidal contraceptives serve an important role in meeting a woman's choice of preferred contraception. Spermicides are chosen by women who wish a simple, safe, readily available contraceptive method that offers many benefits including: self choice and use without partner involvement; easy availability for immediate protection whenever needed, irrespective of interval between use; non-hormonal contraceptive control without affecting menses; and a back-up to a barrier method (i.e., to the condom, cervical cap, diaphragm).

Turning to FDA's question on comparative efficacy labeling on all OTC contraceptive products, it is a matter of long-standing FDA policy that decisions about product availability and label statements should be, "scientifically documented, clinically significant and important to the safe and effective use of the product by the consumer." This is an important three-part hurdle which bears directly on the consideration of comparative effectiveness labeling.

First regarding the initial hurdle of scientific documentation, any decision in OTC labeling requires an evaluation by FDA that the suggested labeling – here relating to comparative effectiveness of vaginal spermicide products – is supported by high quality scientific evidence. This means before comparative effectiveness labeling is recommended for OTC spermicides, which are currently covered under the public OTC Review rulemaking process, FDA should ask for public review and comment to evaluate the quality of the scientific documentation. It also means – if we are considering comparative effectiveness labeling – that as new valid evidence emerges, there is a

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mechanism to expeditiously update the labeling, in order to help ensure competitive fairness in the marketplace.

Second, OTC labeling, as a matter of regulatory policy, only contains the essential information necessary for safe and effective use of the product by the consumer. The two hurdles of clinical significance and importance to the consumer bear on this aspect of essentiality of the information, and the nature of the condition to be treated or prevented relates directly to these considerations. In the case of prevention of pregnancy and the consequences of an unwanted pregnancy, the uniqueness of this condition and its consequence for the unborn, the mother and the father is unparalleled in any self-care category. The life-altering aspects of an unwanted pregnancy are potentially profound. Providing comparative effectiveness information to a woman who is choosing a contraceptive method allows her the best opportunity for self-determination in this unique situation.

On this background, questions to consider in developing comparative effectiveness labeling for OTC spermicide products are:

- Is the proposed labeling consistent with FDA's long-standing policy that label statements must be scientifically documented, clinically significant and important to the safe and effective use of the product by the consumer?
- Is there a sufficiently large database that is adequately scientifically documented to permit reasonable comparisons of product effectiveness for all products with the specific indication under review?
- Does the label statement communicate comparative effectiveness in a consumer friendly and easy to understand way and in a form consistent with FDA's final rule on OTC label content and format?

Hence, CHPA would support a public review and comment process on the issue of comparative effectiveness labeling on OTC spermicides, only because pregnancy is unique in the self-care category and requires special consideration. In the past, CHPA has supported specialized labeling relating to pregnancy, including, for example, use of the OTC pregnancy/nursing statement on OTC products and CHPA's voluntary label statement program for dietary supplements (see CHPA Citizen Petition of March, 2000). However, CHPA does not support comparative effectiveness labeling for other OTC indications and categories, given that they do not rise to the level of uniqueness of the potentially life-altering consequence of failed pregnancy prevention.

We believe a public comment process would be important, because this would provide the best opportunity for all stakeholders to have adequate time to develop input on this important matter. We ask that the questions for consideration that we have raised be included in a *Federal Register* proposal to initiate this process.

We would be pleased to answer any questions you may have.