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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Docket No. FDA–2014–N–0189

RE: FDA proposal not to include reproductive warning on cigars

On page 23168 of the Proposed Rule the FDA states: "FDA is not proposing the fifth FTC warning (Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight), because although cigarette smoking has been shown to cause these health effects and cigar smoke is similar, the Agency is not aware of studies specifically linking cigars to these reproductive effects."

FDA specifically requested comment on its proposal to require the use of only four of the five current FTC warnings for cigars.

The FDA's decision to drop this warning is inconsistent with the FDA's own summary of the scientific evidence on the health effects of tobacco smoke

There is strong scientific evidence to support inclusion of this "fifth" warning, including in Chapter 8, "Reproductive and Developmental Effects," of the 2010 Surgeon General report *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis of Smoking-Attributable Disease*, which is cited as reference 50 in the Proposed Rule.

This chapter demonstrates that *tobacco* smoke causes reproductive and developmental effects. While the epidemiological studies summarized in this chapter are of cigarette smoke, as the FDA itself notes in the Proposed Rule, cigarette and cigar smoke are similar. Moreover, Chapter 8 lists effects of several constituents of smoke (nicotine, carbon monoxide, and polycyclic aromatic hydrocarbons) that are present in cigar smoke.

The State of California maintains a scientifically peer reviewed list of chemicals known to cause reproductive toxicity (appended to this comment and available at http://oehha.ca.gov/prop65/prop65_list/files/P65single050214.pdf) that includes both *tobacco* smoke (primary) and secondhand *tobacco* smoke (ETS) as developmental toxins, as well as many constituents of tobacco smoke, including arsenic, benzene, 1,3-butadiene, cadmium, carbon monoxide, lead, nicotine, and nitrous oxide.

This warning label satisfies the standard in section 906(d) of the Family Smoking Prevention and Tobacco Control Act which allows FDA to issue a regulation to require restrictions on the sale or distribution of a tobacco product if the regulation "would be appropriate for the protection of the

public health." As FDA points out in the proposed rule (79 F.R. 23142 at page 23164), the statute provides that a determination as to whether a regulation requiring a health warning "would be appropriate for the public health must be based on the risks and benefits to the population as a whole (including tobacco users and nonusers )…" There is more than enough evidence that this warning would be appropriate for the public health because, as shown in the scientific literature outlined above, it would provide significant benefits to both users and nonusers of cigar products, and would have no risks. Further, courts give great deference to the FDA's decisions, and a regulation must be upheld unless the Agency's action, findings, or conclusions are found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. (5 U.S.C. section 706(2)(A); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *Ethicon, Inc. v. FDA*, 762 F. Supp. 382, 386 (D.D.C. 1991). Deference is especially due when, as here, the agency is evaluating scientific data within its technical expertise (*Henley v. FDA*, 77 F. 3d 616, 621 (2d Cir. 1996).

For these reasons, the FDA should not exclude the warning about reproductive toxicity.

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