

December 22, 2008

The Honorable Tom Daschle, Secretary-designate
U.S. Department of Health and Human Services
200 Independence Ave. S.W.
Washington, DC 20201

Dear Secretary-designate Daschle:

The European Centre for the Validation of Alternative Methods' (ECVAM) Scientific Advisory Committee (ESAC) announced that it has endorsed two new non-animal methods as stand-alone replacements for assessing skin irritation: the Modified EpiDerm Skin Irritation Test (MatTek Corporation in Ashland, Mass.) and SkinEthic RHE (SkinEthic in Nice, France). PETA Europe is proud to have been a sponsor of the validation studies leading to ECVAM's endorsement. These new methods have improved sensitivity over skin-irritation methods previously endorsed by ECVAM—they do not require verification of negatives in animals, and they complement the widely used non-animal tests for skin corrosivity. Therefore, in Europe, assessment of chemicals for skin corrosivity and skin irritation can be done entirely without the use of animals.

In the U.S., the organization responsible for the validation and recommendation of alternative methods, the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), which is a subdivision of the National Toxicology Program (NTP) under the Department of Health and Human Services (HHS), has yet to evaluate any of these non-animal skin-irritation methods.

As of March 2009, the E.U. Cosmetics Directive 76/768/EEC will prohibit the marketing of any finished cosmetics product or ingredient that has been tested on animals when a valid alternative exists. To meet this deadline, the European Commission has drafted an E.U. test guideline (B.46 *In Vitro* Skin Irritation: Reconstructed Human Epidermis (RHE) Model Test) which is expected to be endorsed by the E.U. Parliament by the end of the year. A similar test guideline is under consideration by the Organization for Economic Coordination and Development (OECD).

As a result of this development, the lack of availability of these assays to U.S. manufacturers becomes a significant barrier to international trade after March 2009. In the interest of global harmonization of regulatory test methods as well as adherence to the principles of the "three R's" (replacement, reduction, and refinement of the use of animals in testing), it is critical that ICCVAM recommends these new skin-irritation methods without delay. Unfortunately, ICCVAM's history to date has been one of inaction and complacency.

We urge you to take an active role in modernizing toxicity testing in the U.S. Thank you for your consideration.

Sincerely,



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cc: The Honorable Michael O. Leavitt, Secretary, HHS



PETA

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