



Department of Pesticide Regulation

13/07/99 #00538A



Gray Davis
Governor

Winston H. Hickox
Secretary for
Environmental
Protection

James W. Wells, Director
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Public Information and Records Integrity Branch
Information Resources and Services Division (7502C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Re: Docket Control Number OPP-00538A

In a Federal Register notice published December 30, 1998, the Environmental Protection Agency solicited comments on a protocol for testing the efficacy of disinfectants used to inactivate Hepatitis B virus and corresponding label claims. This letter provides such comments.

The proposed decision would replace the current chimpanzee infectivity test system (in which the human hepatitis B virus itself is used) with an alternative test system using a surrogate virus (such as the duck hepatitis B virus, DHBV) to test the efficacy of disinfectants in inactivating the human hepatitis B virus (HHBV) and to claim efficacy against HHBV. This proposal would be scientifically valid if the surrogate virus DHBV is proven to be equally resistant or more resistant to the specific disinfectant than the human HBV under the same test conditions. Otherwise, label claims of efficacy against human HBV, or broad label claims such as "effective against HBV" or "Hepadnavirucidal" without adding a qualifying statement or providing information about the test organism would, in our opinion, be misleading.

Also, the proposed Agency's implementation plans for allowing products to be registered with human HBV claims, using surrogate viruses and animal models without confirming the validity of the test protocol and without provisions for a qualifying statement concerning the test organism, would jeopardize public safety. In addition, such practices would be inconsistent with past and existing EPA and

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California Department of Pesticide Regulation registration requirements and policies and would undermine the integrity and credibility of the registration process and would compromise public trust and safety.

The fact that the human HBV belongs to the same taxonomic family (*Hepadnaviridae*) as the duck HBV does not eliminate or minimize the significance of the differences in their host specificity and infectivity. The human HBV is not known to infect ducks and the duck HBV is not known to infect humans.

In summary, the California Department of Pesticide Regulation shares EPA's concern about the continued use of the chimpanzee model and support its efforts to eliminate or minimize the use of the chimpanzee for experimental purposes, provided human safety and public trust are not compromised in the process by allowing unsubstantiated and/or unqualified virucidal claims against human hepatitis B virus or any other virus known to be a human pathogen. It is CDPR's hope that this matter be given careful consideration, particularly in view of its potential far-reaching impact on Federal and state registration requirements and programs.

Sincerely,



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