

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT**

**SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986
(PROPOSITION 65)**

**NOTICE TO INTERESTED PARTIES
February 21, 2003**

**Request for Information on Chemicals to be Considered by the
OEHHA Science Advisory Board's Carcinogen Identification Committee**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) is the lead agency for the implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65; Health and Safety Code Section 25249.5 *et seq.*).

The Carcinogen Identification Committee (CIC) of OEHHA's Science Advisory Board identifies chemicals for addition to the list of chemicals known to the State to cause cancer, which pursuant to Proposition 65 must be updated annually. The Committee serves as the State's qualified experts for determining whether a chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer.

On November 5, 1999, OEHHA announced the final priority assignment for lovastatin as "High" carcinogenicity concern in a notice published in the *California Regulatory Notice Register* (CRNR) (Register 99, No.45-Z). A request for information relevant to the assessment of the evidence of carcinogenicity of lovastatin was published in the CRNR (Register 99, No.47-Z) on November 19, 1999. Information was received and was considered as OEHHA began preparation of the draft hazard identification document.

Subsequent to the selection of lovastatin for draft hazard identification document preparation, a request was received from the counsel representing Merck, the manufacturer of lovastatin, stating that if OEHHA considered it necessary to bring forward lovastatin for consideration by the CIC, then all of the statins should be brought forward simultaneously for evaluation. The reasons advanced by Merck included that: lovastatin is a well-established aid in lowering cholesterol; the review of only lovastatin by the CIC may be misperceived as reflecting a comparative analysis of all statins; a finding regarding lovastatin's carcinogenicity might result in the misinterpretation that among all the statins, lovastatin presents a unique risk of cancer not presented by the other statins.

Consistent with the prioritization procedure which states, "(u)nder exceptional circumstances, the process described in this (prioritization) document may be abbreviated to allow OEHHA to respond to specific public health needs," the Director of OEHHA consulted with the Chair of the CIC about the request made by Merck. Dr. Thomas Mack, CIC Chair, agreed that there was merit to the request. As a result, the issue of whether or not the statin drugs should be considered simultaneously as a group was placed on the agenda as a discussion item at the December 17, 2002 CIC meeting. At that meeting, the CIC recommended that OEHHA, as resources are available, prepare individual hazard identification documents for each of the statin

drugs (atorvastatin calcium, cerivastatin sodium, fluvastatin sodium, lovastatin, pravastatin sodium, and simvastatin) and present them to the CIC at a future meeting. The CIC at that time would consider each of the statin drugs individually for possible listing.

In light of the CIC's recommendation, OEHHA initiates a 60-day data call-in period for the following chemicals:

CHEMICAL	CAS No.
Atorvastatin calcium	134523-03-8
Cerivastatin sodium	143201-11-0
Fluvastatin sodium	93957-55-2
Lovastatin*	75330-75-5
Pravastatin sodium	81131-70-6
Simvastatin	79902-63-9

*Although lovastatin was the subject of a data call-in in November 1999, in an effort to ensure that all relevant scientific information is considered, OEHHA is including lovastatin in this data call-in period. Information submitted during the November 1999 data call-in need not be submitted again.

Interested parties or members of the public wishing to provide information relevant to the assessment of carcinogenicity for these chemicals should forward such information to the address given below. This period will end on **Tuesday, April 22, 2003**. The information received during this data call-in period will be reviewed and considered by OEHHA as it develops the draft cancer hazard identification documents on each of these chemicals.

OEHHA welcomes public participation and public input as part of these scientific assessments. Notification of the availability of the hazard identification documents and of the time, date, location, and agenda of the meeting of the CIC where these chemicals will be considered will also be provided in subsequent notices published in the CRNR and posted on the OEHHA web site at www.oehha.ca.gov. It is anticipated that the draft hazard identification documents will be made available for a 60-day comment period prior to the Committee meeting at which these chemicals will be considered.

Relevant information on these chemicals should be sent in triplicate by mail or fax to:

Cynthia Oshita
Office of Environmental Health Hazard Assessment
Proposition 65 Implementation
P.O. Box 4010
1001 I Street, 19th floor
Sacramento, California 95812-4010
FAX (916) 323-8803
(916) 445-6900

In order to be considered, the relevant information must be postmarked (if sent by mail) or received at OEHHA (if delivered in person or sent by FAX) by 5:00 p.m. on Tuesday, April 22, 2003.