



Special Notice

STATE BOARD
OF EQUALIZATION

California Sales and Use Tax Regulation 1591 *Medicines and Medical Devices*

450 N Street
Sacramento
California 95814

Regulation 1591 has been reorganized into five separate regulations based on subject matter. Some provisions have also been reinterpreted and expanded. The following information highlights those provisions believed most significant to pharmaceutical companies. —Editor

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Medicines Provided by Pharmaceutical Companies — In General

Amended Regulation 1591, subdivision (e)(4) provides that tax does not apply to the storage, use, or consumption of medicines in California when such medicines are furnished by a pharmaceutical manufacturer or distributor *without charge* to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research when the sample medicines furnished are (1) of a type that can be dispensed only on prescription by persons authorized to prescribe *and* (2) for the treatment of a human being.

The exemption from use tax includes the cost of the materials used to package the sample medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the cost of elements and ingredients used to produce the samples. This is true whether the pharmaceutical company or distributor purchases the items outside the state or using a resale certificate in California.

When a pre-filled syringe or similar delivery device is used to package and contain a sample medicine, as well as to inject or otherwise administer the medicine to the patient, the exemption from tax is *not* lost due to the fact that the device is used for a dual purpose. However, tax does apply to the use of *empty* syringes or similar delivery devices furnished separately or included in the packages with the sample medicines.

Medicines Provided by Pharmaceutical Companies — Clinical Trial Medicines

The exemption provided under Regulation 1591, subdivision (e)(4) applies in the same manner to the *use* of “clinical trial medicines” during the United States Food and Drug Administration’s drug development and approval process (beginning with phase 1 of the clinical trials) when the experimental drugs are furnished and used as discussed below.

“Clinical trial medicines” are substances or preparations approved by the United States Food and Drug Administration as “Investigational New Drugs” intended for treatment and application to the human body. These experimental drugs are furnished by pharmaceutical developers, manufacturers, or distributors to *licensed physicians* and subsequently dispensed, furnished, or administered during the clinical trial process as ordered by the licensed physicians.

The exemption discussed above does not apply to experimental drugs furnished during the *preclinical* testing phase. These tests are performed prior to receiving approval to test the drugs on human beings. Also, clinical trial medicines do not include placebos. Since placebos are not used in the *treatment* of human beings, their use is subject to tax.

■ For More Information

If you have questions regarding this notice or the regulations, please call our Information Center at 1-800-400-7115. Staff are available from 8:00 A.M. to 5:00 P.M., Monday through Friday, except State holidays. If you would like copies of the regulations or this notice, please call our Information Center or visit our Internet site at www.boe.ca.gov.