



**STATE BOARD OF EQUALIZATION**

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February 16, 1993

BURTON W. OLIVER  
*Executive Director*

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Re: ---

Dear ---:

This is in response to the questions which we discussed when we met on December 1, 1992, as well as a response to the letter from ---, dated December 1, 1992.

We understand that A manufactures two products marketed under the trade names X and Y. Both products are prescription drugs, exempt from the sales and use taxes under Revenue and Taxation Code section 6369. You requested a written opinion as to whether certain materials used in the manufacture of these products are exempt under Regulation 1525(b) as being incorporated into the manufactured product. You also requested our opinion as to whether certain packaging and shipping materials are exempt under Regulation 1589(b)(1)(A).

X

X is a recombinant form of the naturally occurring protein erythropoietin. In the human body, erythropoietin is produced primarily in the kidneys in response to a low blood cell level. X is used to treat anemia associated with chronic renal (kidney) failure.

X is produced using a series of production processes:

1. A small vial of genetically engineered Chinese hamster ovarian cells is thawed and inoculated with the gene for human erythropoietin. In approximately five weeks, these cells are grown to a sizable volume, and contained in a large stainless steel fermentor.

2. Cell cultures are produced by the use of roller bottles (to continue the cell growth process) and diafiltration whereby erythropoietin is collected after the cells secrete it into the nutrient media.

3. The collected erythropoietin is frozen in a quarantine freezer, tested to establish the protein quality, and purified. The purification process uses the electrical charge, size, weight and other properties of the erythropoietin molecule to separate it from other materials.

4. In the last phase, it is formulated into various dosage strengths, vialled for shipment, and packed in blue ice, foam and styrofoam.

## Y

Y is a recombinant form of human G-CSF (granulocyte colony-stimulating factor) which stimulates the production of neutrophils, a specific type of white blood cell which attacks and destroys bacteria. If a person's neutrophil level is too low, a Y injection can stimulate the bone marrow to produce more.

Y is produced from E-coli cells which are genetically engineered to produce G-CSF. The process is similar to the production of X. It begins with the fermentation of G-CSF seed stock. The cells are grown, fermented and purified in bulk form, and then formulated into prescribed concentrations and vialled.

## **Use of Tangible Personal Property**

The manufacturing processes described above involve the use of tangible personal property, some of which is physically incorporated into the finished products, and some of which is only used and consumed in the process. The lists of products, as contained in your computer output includes serum, yeast extracts, and nutrients used for inoculation, cell growth and fermentation processes which form the bulk proteins from which X and Y are formulated. Although only minute traces of these materials are found in the finished product and are not visible, they do become a part of the finished product, for purposes of Regulation 1525(b), and are not subject to tax.

Also in your list are materials which are not for the purpose of incorporation into the final product, but are for use in the manufacturing process and are consumed during that process. These would include items such as buffers, separating agents, cleaning agents, agents that kill cells or detach the cells from a flask, ph control agents, and anti-foam agents. These materials are taxable to you, as the consumer, when you purchase them, pursuant to Regulation 1525(a).

The third category concerns containers, packaging material, and labels. Under Regulation 1589(b)(1)(A), such items are not taxable when you purchase them, and under Regulation 1589(b)(1)(C), are not taxable when sold by you if sold with nontaxable contents.

Tax does apply to shipping tags and advertising inserts, under Regulation 1589(c).

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Copies of each of these regulations are enclosed for your files. If you have further questions, please contact me.

Sincerely yours,

Donald L. Fillman  
Tax Counsel

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