



440.1893

STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION

916-445-3723

May 3, 1988

REDACTED TEXT

Dear REDACTED TEXT:

On REDACTED TEXT to discuss application of the California Sales and Use Tax Law to the production of certain protein medical products using DNA recombinant technologies.

REDACTED TEXT.

Product development first requires the identification and then sequencing of the desired protein. DNA recombination results in a recombinant molecule which is inserted into an appropriate host. Following plasmid integration, DNA replication and cloning, a host population capable of protein expression is produced. Ultimately, large scale fermentation methods are employed in order that commercial quantities of product may be produced. Following recovery, purification and packaging, the product is ready for sale for clinical use.

Sales to distributors qualify as sales for resale and are nontaxable. Sales for clinical use are exempt as sales of prescription medicine pursuant to Revenue and Taxation Code Section 6369.

Our discussion focused on the commercial fermentation process. Cell growth and product expression occur in large vessels. Growth of the cell population to production scale is facilitated by maintaining the cells in a fluid which mimics the serum environment. Maintenance and growth of the population require the addition to the vessel of nutrients, of growth factors, of antibiotics, of products that protect the cells from mechanical damage during mixing, and of other properties. Any product introduced into the mix which becomes, or a fraction of which becomes, a component of the ultimate protein product can be traced at the atomic level.

Presently REDACTED TEXT is purchasing on a tax-paid basis all ingredients entered into the fermentation vessels, notwithstanding the fact that a protein product produced in the vessel is sold by REDACTED TEXT in the regular course of its business.

As we discussed, our Regulation 1525, "Property Used in Manufacturing," provides as follows:

"(A) Tax applies to the sale of tangible personal property to persons who purchase it for the purpose of use in manufacturing, producing or processing tangible personal property and not for the purpose of physically incorporating it into the manufactured article to be sold. Examples of such property are machinery, tools, furniture, office equipment, and chemicals used as catalysts or otherwise to produce a chemical or physical reaction such as the production of heat or the removal of impurities.

"(b) Tax does not apply to sales of tangible personal property to persons who purchase it for the purpose of incorporating it into the manufactured article to be sold, as, for example, any raw material becoming an ingredient or component part of the manufactured article."

If the fermentation process did not involve living cells and metabolic processes, application of Regulation 1525 would be clear. Any item introduced into the vessel which was physically incorporated, or a part of which was physically incorporated, into the protein to be resold could be purchased for resale. All other products would be taxable when sold to REDACTED TEXT.

The question is whether the result in this case is governed by different rules because living cells and metabolic processes are used to produce the protein product.

As we discussed REDACTED TEXT some guidance is available from Revenue and Taxation Code Section 6358, which provides a sales tax exemption as follows:

"(b) Feed for any form of animal life of a kind the products of which ordinarily constitute food for human consumption, or are to be sold in the regular course of business.

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"(d) Fertilizer to be applied to land the products of which are to be used as food for human consumption or sold in the regular course of business."

The express inclusion of this exemption in the Sales and Use Tax Law implies that generally nutrients for living matter are taxable when sold as nutrients, even though the living matter, or products of the living matter, may be sold in the regular course of business, unless the terms of the exemption are met.

The suggestion is that "feed" for human food "animal" cells could qualify for exemption but not "feed" for other living cells. Likewise, nutrients for plant life would qualify for exemption only if the nutrients were applied to land.

As you are aware, however, the issue in question before us here was dealt with by us well before the development of the new biotechnology technologies REDACTED TEXT. As early as July 30, 1954, we issued the following opinion:

"Corn steep liquor and crude milk sugar (lactose) purchased for use in the production of penicillin become component parts of the penicillin. Accordingly,

such purchases are not subject to sales or use tax when used in the production of penicillin for resale.”

Penicillin is an antibiotic compound obtained from the filtrates of certain molds, such as Penicillin notatum. In traditional taxonomies, molds are not classified as animal life.

It is apparent that in considering the question of property purchased for resale in the context of cellular expression of biological products we have not applied the macroscopic rule of metabolic production of Section 6358 to the microscopic world of metabolic production of the pharmaceutical industry. Indeed, it seems only reasonable that whether a protein or similar biological product is produced by wholly synthetic or more natural means, the tax consequences of the production should not differ. Regardless of the technology used, properties which become, in whole or in part, a part of a protein to be resold ought to be treated for sales tax purposes as having been purchased for resale.

Applying this principle to the case before us, it is our opinion that the analysis which we must make is the same analysis that would be made if your product was produced by a nonmetabolic process. You may purchase for resale properties which physically contribute to the end product which you sell. You may not purchase for resale products which are introduced into the vessels and contribute to the success of the fermentation process but which are not resold. The cells themselves may not be purchased for resale.

We understand that REDACTED TEXT has been purchasing all properties utilized in the commercial production operation on a tax-paid basis. Where the sale transactions were subject to sales taxes, your vendors would be entitled to a refund, upon condition that the refunds are paid over to you. Where the sale transactions were subject to use tax, REDACTED TEXT could apply directly to this Board for a refund. Any claim for refund would be subject to the three-year limitation period. Refunds would be appropriate only with respect to property purchased in contemplation of commercial production, i.e. in contemplation of resale. The resale certificate procedure should be used for future purchases.

Very truly yours,

Gary J. Jugum
Assistant Chief Counsel

GJJ:sr