AMENDMENT TO H.R. 1937 OFFERED BY MR. RAILSBACK

ASPARTAME

At the bottom of page 8, line 23, change the period to a comma strike the quotation mark, and add the following:

> except that for products approved and for which a stay of regulation granting approval pursuant to Section 409 of the Federal Food, Drug and Cosmetic Act was in effect as of January 1, 1981, the period of such patent extensions shall be measured from the date such stay was imposed until such proceedings are finally resolved and commercial marketing permitted provided the filing required by (b)(1) is made within 90 days of the termination of the regulatory review period or the effective date of this section whichever is later."

EXPLANATION OF THE RAILSBACK AMENDMENT TO H.R. 1937 - 3/25/82

ASPARTAME

Background

In 1974 the Food and Drug Administration approved the sale of Aspartame, a low-calorie, dry sweetener developed by G.D. Searle & Co. However, that approval was stayed in 1975 when questions were raised about the food additive's safety and about certain test results. In the summer of 1981, after more than five years, that stay was lifted and Searle began marketing Aspartame in October. Aspartame was previously approved for sale in France, Belgium, Mexico and other countries.

It should be noted that after imposing the stay of its approval of Aspartame, the FDA asked an independent panel of medical school pathologists to evaluate Aspartame, and in December of 1978 that panel affirmed the Searle testing and recommended the stay be lifted. Unwilling to accept the report of its panel, the FDA named a Public Board of Inquiry (PBOI) to study Aspartame in June 1979. The PBOI report was filed toward the end of 1980 and, after a delay of some months, the FDA announced it would lift the stay.

Legislation

The Senate passed the Patent Term Restoration Act, S. 255, which is designed to provide that the patent term of drugs, chemicals, food additives, etc., that have significant pre-marketing clearance. The Senate-passed bill includes an amendment adopted without objection to permit recapture of the

more than five years of patent life of Aspartame that were lost during the period that the stay was in effect. This amendment does not seek to recapture retroactively either the routine pre-market clearance time spent on Aspartame, nor the time during which Searle voluntarily withheld the product from the market. S. 255, as passed by the Senate, is identical to H.R. 1937, the Patent Term Restoration bill pending in the House, with the exception of the amendment concerning Aspartame.

UNDERLYING ISSUE

The Patent Restoration Act is essentially a prospective piece of legislation, while the Aspartame amendment, offered in the Senate by Senator Heflin, does retroactively restore five and a half years of lost patent life to this product. It should be noted that Aspartame was patented in 1970 and the patent will otherwise expire in 1987, giving Searle less than six years of the traditional 17-year patent life. The argument is simply that the prolonged FDA stay, which all subsequent scientific evidence found to be unnecessary, has unjustly robbed Searle of more than five years of its patent right. There are no precedents for a stay of this type and duration, nor for the PBOI. While Searle does not seek patent restoration retroactively for the routine FDA testing, it does seek restoration for the period of the stay as a simple matter of equity.

Moreover, and quite importantly, if the patent life is not extended, Searle will face a difficult decision on whether or not to undertake costly research to solve problems with

use of Aspartame in soft drinks and in cases where it would undergo significant heat. At present, the compound breaks down if it is in solution for too long or exposed to heat such as that experienced in baking. Unless these problems are solved, the availability of this important product for diabetics and others who must restrict their intake of sugar will be limited. Extending the patent life of Aspartame, then, provides a real and a necessary incentive to important and potentially valuable research.