H.R. 1937

3/22/82 -1-

KASTENMEIER - FRANK

AMENDMENT NUMBER SIX

On page 8, after line 23 insert the following:

"In the event the regulatory review period has commenced prior to the effective date of this section, then the period of patent extension for such product or a method of using such product shall be measured from the effective date of this section; provided, however that in the event that prior to the effective date of this section, a new drug product was approved on a date more than seven years after the commencement of the regulatory review period and during said regulatory review period the patentee was notified that said product's application was not approvable under Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act and as a result of which the patentee caused a major health or environmental effects test to be conducted to evaluate carcinogenic potential, then the period of patent extension for said product or the method of use of such product shall be seven years, provided further that the filing required by subsection (b)(1) hereof is made within ninety days of the effective date of this section.

EXPLANATION

This amendment provides equitable relief to a patentee who suffered extraordinarily egregious and unwarranted regulatory delay.