3/22/82

17.12.1937

KASTENMEIER -1-

AMENDMENT NUMBER THREE

On page 5, lines 8 through 10, delete "food additive, color additive, new animal drug, veterinary biological product, device new"

On page 5, lines 13 through 21 delete, "(i) initiated a major health or environmental effects test on such product or a method for using such product, (ii) claims an exemption for investigation or requests authority to prepare an experimental product with respect to such product or method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (iii)" and insert in lieu thereof the following:

"(i) initiated a clinical ~~trial~~ investigation on humans for the specific method for use for which such product is approved or licensed under such statutes, or (ii)"

On page 6, after line 9, insert the following:

(B) With respect to a food additive or color additive, a period commencing on the earliest of the date the recipient of marketing approval (i) claimed an exemption for investigation with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, or (ii) submitted a petition for regulation with respect to such

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(continued)

product or a method for using such product is approved or licensed under such statute;

(C) With respect to an animal drug or veterinary biological product, a period commencing on the earlier of the date the recipient of marketing approval (i) initiated a test on the animal for which the use of the product has been approved wherein the test required at least six months to conduct not including any period for analysis or conclusions and the data from which is included in the application or petition with respect to such product or a method for using such product under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Act of Congress of March 4, 1913, or (ii) submitted an application or petition with respect to such product or method under such statutes, and ending on the date such application or petition with respect to such product or a method for using such product is approved or licensed under such statutes;

(D) With respect to a device, a period commencing on the earlier of the date the recipient of marketing approval (i) submitted a proposed product development protocol with respect to such product or method for using such product under

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(continued)

the Federal Food, Drug, and Cosmetic Act, or (ii) submitted an application with respect to such product or method for using such product under such statute, and ending on the date such application with respect to such product or a method for using such product is approved under such statute;

On page 6, on line 10, delete, "(B)" and insert "(E)", on line 23 delete "(C)" and insert "(F)".

EXPLANATION

The purpose of this amendment is to identify a point in time where the serious clinical and financial commitment which is necessary to meet regulatory requirements actually begins. The amendment is predicated on the view that this point in time for pharmaceutical products is the initiation of human clinical tests, rather than the initiation of animal tests or the filing of the IND application which is arbitrary and very much under the control of the applicant for regulatory approval. The amendment is intended to identify as narrowly as possible that period of time during which a pharmaceutical developer loses effective patent life due to testing which is required to meet the safety and efficacy requirements of the Food and Drug Administration.

Similar modifications are made to the legislation with respect to the commencement of term of patent restoration for food and color additives, animal drugs and medical devices.