AMENDMENT NO._____ Calendar No._____

Purpose: To clarify the information required to support administrative order requests with respect to OTC monograph drugs.

IN THE SENATE OF THE UNITED STATES—119th Cong., 1st Sess.

S. 2292

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user fee program for over-thecounter monograph drugs, and for other purposes.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. KIM (for himself and Mr. BANKS)

Viz:

At the appropriate place, insert the following:

SEC. ___. INFORMATION TO SUPPORT ADMINISTRATIVE ORDER REQUESTS.

(a) IN GENERAL.—Section 505G of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h), as amended by section 6(a), is further amended by adding at the end the following:

"(s) INFORMATION TO SUPPORT ADMINISTRATIVE ORDER REQUESTS.—

"(1) LEAST BURDENSOME APPROACH.—

"(A) IN GENERAL.—With respect to an order requested pursuant to subsection (b)(5), the Secretary shall consider, as appropriate, the least burdensome means of evaluating whether the drug described in the request is generally recognized as safe and effective under section 201(p)(1).

"(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed to alter, supersede, or limit the criteria—

"(i) for determining under subsection (b)(5)(A) whether a request is sufficiently complete and formatted to permit a substantive review; or

"(ii) for determining whether a drug is generally recognized as safe and effective under section 201(p)(1).

"(2) MEETINGS WITH SPONSORS.—

"(A) IN GENERAL.—In the case of an order requested pursuant to subsection (b)(5), and where published reports are insufficient to support the requested findings, the Secretary shall meet with the requestor upon a reasonable written request, for the purpose of discussing the types of evidence necessary, including, if ap-

propriate, the design and size of any study to support a demonstration that the drug is generally recognized as safe and effective.

"(B) RECORDS OF MEETINGS.—The Secretary shall—

"(i) provide to the requestor, in writing—

"(I) the minutes of any meeting described in subparagraph (A);

"(II) any recommendations regarding the parameters of any study described in subparagraph (A) and discussed pursuant to a meeting described in such subparagraph; and

"(III) a summary of the meeting discussion; and

"(ii) make the summary of the meeting discussion described in clause (i)(III) part of the administrative record.".

(b) PROCEDURE FOR MINOR CHANGES.—Section 505G(c)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355h(c)(1)) is amended, in the matter preceding subparagraph (A), by inserting ", including a change from one oral dosage form to another oral dosage form," after "subsection (b)".