I

116TH CONGRESS
1ST SESSION

H. R. 2387

To amend subsection (q) of section 505 of the Federal Food, Drug, and Cosmetic Act to clarify the process for denying certain petitions whose primary purpose is to delay the approval of an application submitted under subsection (b)(2) or (j) of such section 505, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 2019

Mr. LEVIN of Michigan (for himself and Mr. ROONEY of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend subsection (q) of section 505 of the Federal Food, Drug, and Cosmetic Act to clarify the process for denying certain petitions whose primary purpose is to delay the approval of an application submitted under subsection (b)(2) or (j) of such section 505, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Stop The Overuse of Petitions and Get Affordable Medicines to Enter Soon Act of 2019'' or the ''STOP GAMES Act of 2019''.

SEC. 2. DENIAL OF PETITIONS WHOSE PRIMARY PURPOSE IS TO DELAY APPROVAL OF CERTAIN APPLICATIONS.

(a) IN GENERAL.—Subparagraph (E) of section 505(q)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1)) is amended to read as follows:

''(E) DENIAL BASED ON INTENT TO DELAY.—

''(i) IN GENERAL.—If the Secretary determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application or the petition does not on its face raise valid scientific or regulatory issues, the Secretary may deny the petition at any point based on such determination.

''(ii) FACTORS.—The Secretary may issue guidance to describe the factors that will be used to determine under this subparagraph whether a petition is submitted with the primary purpose of delaying the

approval of an application. Such factors shall include the following:

"(I) Submission of a petition where it appears, based on the date that relevant information relied upon in the petition became known to the petitioner (or reasonably should have been known to the petitioner), that the petitioner has taken an unreasonable length of time to submit the petition.

"(II) Submission of multiple or serial petitions raising issues that reasonably could have been known to the petitioner at the time of submission of the earlier petition or petitions.

"(III) Submission of a petition close in time to a known, first date upon which an application under subsection (b)(2) or (j) of this section or under section 351(k) of the Public Health Service Act could be approved (such as submission close in time to the expiration of a blocking patent or exclusivity).

"(IV) Submission of a petition without any data or information in support of the scientific positions set forth in the petition.

"(V) Submission of a petition raising the same or substantially similar issues as a prior petition to which the Food and Drug Administration has already substantively responded, particularly where the subsequent submission closely follows in time the earlier response.

"(VI) Submission of a petition concerning standards for approval of a drug product for which—

"(aa) the Food and Drug Administration has provided an opportunity for public input (such as when the Food and Drug Administration has issued draft or final product-specific guidance applicable to the drug product); and

''(bb) the petitioner has not provided comment other than through the petition.

''(VII) Submission of a petition requesting that other applicants must meet standards for testing, data, or labeling for their products that are more onerous or rigorous than the standards applicable to the applicable listed drug or the petitioner's version of the same product.

''(VIII) Other relevant considerations, including the history of the petitioner with the Food and Drug Administration (such as whether the petitioner has a history of submitting petitions which the Food and Drug Administration has determined were submitted with the primary purpose of delay).

''(iii) REFERRAL TO FTC.—If the Secretary determines that a petition has been submitted with the primary purpose of delaying the approval of an application, as described in clause (i), the Secretary shall

refer the matter to the Federal Trade Commission.''.

(b) DEADLINE FOR SUBMISSION OF PETITIONS.—

(1) DEADLINE.—Clause (i) of section 505(q)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1)(A)) is amended to read as follows:

''(i) the request is in writing, is a petition submitted to the Secretary pursuant to section 10.30, 10.31, or 10.35 of title 21, Code of Federal Regulations (or any successor regulations), and is submitted not later than 60 days after the information upon which the petition is based first became known to the party on whose behalf the petition is submitted; and''.

(2) CERTIFICATION.—Section 505(q)(1)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1)) is amended by striking ''I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: _____.'' and inserting ''I further certify that the information upon which I have based the action requested herein first

became known to the party on whose behalf this petition is submitted on or about _____, which date was not more than 60 days before the date of submitting this petition.''.

(c) REPORTING TO CONGRESS.—Section 505(q)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(3)) is amended—

(1) in the matter before subparagraph (A), by striking ''specifies'';

(2) in subparagraphs (A), (B), (C), and (D), by striking ''the number'' and inserting ''specifies the number'';

(3) in subparagraph (C), by striking ''and'' at the end;

(4) in subparagraph (D), by striking the period at the end and inserting ''; and''; and

(5) by adding at the end the following:

''(E)(i) lists each petition submitted during such period and, for each, identifies the petitioner;

''(ii) quantifies the time and resources expended on each such petition;

''(iii) states the timing of the petition relative to the expiration date of the patents specified in the pending application in the certifi-

cation under subsection (b)(2)(A) or (j)(2)(A)(vii), as applicable;

''(iv) quantifies the delay, if any, caused by any such petition on the approval of any application submitted under subsection (b)(2) or (j), including a description of how any such delay is calculated and an estimate of when any delayed approval would have been granted absent the petition; and

''(v) in cases in which a pending application and a petition with respect to such pending application are disposed of on the same or nearly the same date, states when the Food and Drug Administration would have disposed of the pending application absent the petition.''.

○