

119TH CONGRESS
2^D SESSION

H. R. 8908

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

MAY 19, 2026

Mr. SORESEN (for himself and Mrs. BICE) 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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Stop The Overuse of
5 Petitions and Get Affordable Medicines to Enter Soon Act
6 of 2026” or the “STOP GAMES Act of 2026”.

1 **SEC. 2. DENIAL OF PETITIONS WHOSE PRIMARY PURPOSE**
2 **IS TO DELAY APPROVAL OF CERTAIN APPLI-**
3 **CATIONS.**

4 (a) IN GENERAL.—Section 505(q)(1) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)(1))—

6 (1) in subparagraph (A), by amending clause (i)
7 to read as follows:

8 “(i) the request is in writing, is a pe-
9 tition submitted to the Secretary pursuant
10 to section 10.30, 10.31, or 10.35 of title
11 21, Code of Federal Regulations (or any
12 successor regulations), and is submitted
13 not later than the date that is 60 days
14 after the information upon which the peti-
15 tion is based first became known to the
16 party on whose behalf the petition is sub-
17 mitted; and”;

18 (2) by amending subparagraph (E) to read as
19 follows:

20 “(E) DENIAL BASED ON INTENT TO
21 DELAY.—

22 “(i) IN GENERAL.—If the Secretary
23 determines that a petition or a supplement
24 to the petition was submitted with the pri-
25 mary purpose of delaying the approval of
26 an application or the petition does not on

1 its face raise valid scientific or regulatory
2 issues, the Secretary may deny the petition
3 at any point based on such determination.

4 “(ii) FACTORS.—The Secretary may
5 issue guidance to describe the factors that
6 will be used to determine under this sub-
7 paragraph whether a petition is submitted
8 with the primary purpose of delaying the
9 approval of an application. Such factors
10 shall include the following:

11 “(I) Submission of a petition
12 where it appears, based on the date
13 that relevant information relied upon
14 in the petition became known to the
15 petitioner (or reasonably should have
16 been known to the petitioner), that
17 the petitioner has taken an unreason-
18 able length of time to submit the peti-
19 tion.

20 “(II) Submission of multiple or
21 serial petitions raising issues that rea-
22 sonably could have been known to the
23 petitioner at the time of submission of
24 the earlier petition or petitions.

1 “(III) Submission of a petition
2 close in time to a known, first date
3 upon which an application under sub-
4 section (b)(2) or (j) of this section or
5 under section 351(k) of the Public
6 Health Service Act could be approved
7 (such as submission close in time to
8 the expiration of a blocking patent or
9 exclusivity).

10 “(IV) Submission of a petition
11 without any data or information in
12 support of the scientific positions set
13 forth in the petition.

14 “(V) Submission of a petition
15 raising the same or substantially simi-
16 lar issues as a prior petition to which
17 the Food and Drug Administration
18 has already substantively responded,
19 particularly where the subsequent sub-
20 mission closely follows in time the ear-
21 lier response.

22 “(VI) Submission of a petition
23 concerning standards for approval of
24 a drug product for which—

1 “(aa) the Food and Drug
2 Administration has provided an
3 opportunity for public input
4 (such as when the Food and
5 Drug Administration has issued
6 draft or final product-specific
7 guidance applicable to the drug
8 product); and

9 “(bb) the petitioner has not
10 provided comment other than
11 through the petition.

12 “(VII) Submission of a petition
13 requesting that other applicants must
14 meet standards for testing, data, or
15 labeling for their products that are
16 more onerous or rigorous than the
17 standards applicable to the applicable
18 listed drug or the petitioner’s version
19 of the same product.

20 “(VIII) Other relevant consider-
21 ations, including the history of the pe-
22 titioner with the Food and Drug Ad-
23 ministration (such as whether the pe-
24 titioner has a history of submitting
25 petitions which the Food and Drug

1 Administration has determined were
2 submitted with the primary purpose of
3 delay).

4 “(iii) REFERRAL TO FTC.—If the Sec-
5 retary determines that a petition has been
6 submitted with the primary purpose of de-
7 laying the approval of an application, as
8 described in clause (i), the Secretary shall
9 refer the matter to the Federal Trade
10 Commission.”;

11 (3) by striking subparagraph (F);

12 (4) by redesignating subparagraphs (G)
13 through (I) as subparagraphs (F) through (H), re-
14 spectively;

15 (5) in subparagraph (G), as so redesignated, by
16 striking “‘I further certify that the information
17 upon which I have based the action requested herein
18 first became known to the party on whose behalf
19 this petition is submitted on or about the following
20 date: _____.’” and inserting “‘I
21 further certify that the information upon which I
22 have based the action requested herein first became
23 known to the party on whose behalf this petition is
24 submitted on or about _____,

1 which date was not more than 60 days before the
2 date of submitting this petition.’”]; and

3 (6) in subparagraph (H), as so redesignated, by
4 striking “‘submission of this petition’” and insert-
5 ing “‘submission of this document’”.

6 (b) EXHAUSTION OF ADMINISTRATIVE REMEDIES.—
7 Section 505(q)(2) of the Federal Food, Drug, and Cos-
8 metic Act (21 U.S.C. 355(q)(2)) is amended—

9 (1) in subparagraph (A)—

10 (A) in the heading, by striking “WITHIN
11 150 DAYS”;

12 (B) in clause (i), by striking “during the
13 150-day period referred to in paragraph
14 (1)(F),”; and

15 (C) by amending clause (ii) to read as fol-
16 lows:

17 “(ii) on or after the date that is 151
18 days after the date of submission of the
19 petition, the Secretary approves or has ap-
20 proved the application that is the subject
21 of the petition without having made such a
22 final decision.”; and

23 (2) by amending subparagraph (B) to read as
24 follows:

1 “(B) DISMISSAL OF CERTAIN CIVIL AC-
2 TIONS.—

3 “(i) PETITION.—If a person files a
4 civil action against the Secretary in which
5 a person seeks to set aside, delay, rescind,
6 withdraw, or prevent submission, review, or
7 approval of an application submitted under
8 subsection (b)(2) or (j) of this section or
9 section 351(k) of the Public Health Service
10 Act without first submitting a petition to
11 the Secretary under paragraph (1) that de-
12 scribes all information and arguments that
13 form the basis of the relief requested in
14 such civil action, the court shall dismiss
15 without prejudice the action for failure to
16 exhaust administrative remedies.

17 “(ii) TIMELINESS.—If a person files a
18 civil action against the Secretary in which
19 a person seeks to set aside, delay, rescind,
20 withdraw, or prevent submission, review, or
21 approval of an application submitted under
22 subsection (b)(2) or (j) of this section or
23 section 351(k) of the Public Health Service
24 Act after the date described in paragraph
25 (1)(A)(i), the court shall dismiss with prej-

1 udice the action for failure to timely file a
2 petition.

3 “(iii) FINAL RESPONSE.—If a civil ac-
4 tion is filed against the Secretary with re-
5 spect to any issue raised in a petition time-
6 ly filed under paragraph (1) in which the
7 petitioner requests that the Secretary take
8 any form of action that could, if taken, set
9 aside, delay, rescind, withdraw, or prevent
10 submission, review, or approval of an appli-
11 cation submitted under subsection (b)(2)
12 or (j) of this section or section 351(k) of
13 the Public Health Service Act before the
14 Secretary has taken final agency action on
15 the petition within the meaning of sub-
16 paragraph (A), the court shall dismiss
17 without prejudice the action for failure to
18 exhaust administrative remedies.”.

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

22 (1) in the matter before subparagraph (A), by
23 striking “specifies”;

1 (2) in subparagraphs (A), (B), (C), and (D), by
2 striking “the number” and inserting “specifies the
3 number”;

4 (3) in subparagraph (C), by striking “and” at
5 the end;

6 (4) in subparagraph (D), by striking the period
7 at the end and inserting “; and”; and

8 (5) by adding at the end the following:

9 “(E)(i) lists each petition submitted during
10 such period and, for each, identifies the peti-
11 tioner;

12 “(ii) quantifies the time and resources ex-
13 pended on each such petition;

14 “(iii) states the timing of the petition rel-
15 ative to the expiration date of the patents speci-
16 fied in the pending application in the certifi-
17 cation under subsection (b)(2)(A) or
18 (j)(2)(A)(vii), as applicable;

19 “(iv) quantifies the delay, if any, caused by
20 any such petition on the approval of any appli-
21 cation submitted under subsection (b)(2) or (j),
22 including a description of how any such delay is
23 calculated and an estimate of when any delayed
24 approval would have been granted absent the
25 petition; and

1 “(v) in cases in which a pending applica-
2 tion and a petition with respect to such pending
3 application are disposed of on the same or near-
4 ly the same date, states when the Food and
5 Drug Administration would have disposed of
6 the pending application absent the petition.”.

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