
Guidance for Industry

Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

Procedural

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Guidance for Industry

Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

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**U.S. Department of Health and Human Services
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TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	BACKGROUND	2
A.	Scope of Section 505(q)	2
B.	Determination of Delay	2
C.	Certification and Verification	3
D.	Final Agency Action	3
E.	Judicial Review	3
F.	Exceptions and Reporting	4
III.	DISCUSSION	4
A.	How Does FDA Determine if Section 505(q) Applies to a Particular Petition?	4
1.	<i>Petition Submitted on or after September 27, 2007</i>	5
2.	<i>Petition Submitted in Writing and Pursuant to § 10.30 or 10.35</i>	5
3.	<i>ANDA or 505(b)(2) Application Is Pending at the Time the Petition Is Submitted</i>	6
4.	<i>Petition Requests an Action That Could Delay Approval of a Pending ANDA or 505(b)(2) Application</i>	7
5.	<i>Petition Does Not Fall Within Any of the Exceptions Described in Section 505(q)(4)</i>	7
B.	How Does FDA Determine if a Petition Would Delay Approval of an ANDA or 505(b)(2) Application?	7
C.	How Does FDA Apply the Certification Requirements in Section 505(q)(1)(H)?	9
D.	How Does FDA Apply the Verification Requirements in Section 505(q)(1)(I)?	10
E.	What Is the Relationship Between the Review of Petitions Under Section 505(q) and the Review of ANDAs and 505(b)(2) Applications for Which the Agency Has Not Yet Made a Final Decision on Approvability?	11

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Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides information regarding FDA's (or the Agency's) current thinking on interpreting section 914 of Title IX of the Food and Drug Administration Amendments Act (FDAAA).² Section 914 of FDAAA adds new section 505(q) to the Federal Food, Drug, and Cosmetic Act (the Act)³ and governs certain citizen petitions and petitions for stay of Agency action that request that FDA take any form of action related to a pending application submitted under section 505(b)(2) or 505(j) of the Act.⁴

This guidance describes FDA's interpretation of section 505(q) regarding how the Agency determines if (1) the provisions of section 505(q) addressing the treatment of citizen petitions and petitions for stay of Agency action (collectively, petitions) apply to a particular petition and (2) a petition would delay approval of a pending abbreviated new drug application (ANDA) or 505(b)(2) application. This guidance also describes how FDA interprets the provisions of section 505(q) requiring that (1) a petition include a certification and (2) supplemental information or comments to a petition include a verification⁵ and addresses the relationship between the review of petitions and pending ANDAs and 505(b)(2) applications for which the Agency has not yet made a decision on approvability.

¹ This guidance has been prepared by the Office of Regulatory Policy in the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration.

² Public Law 110-85 (as amended by Public Law 110-316).

³ 21 U.S.C. 355(q). For brevity, in this guidance, references to section 505(q) of the Act are cited as section 505(q).

⁴ 21 U.S.C. 355(b)(2) and (j). In this guidance, an application submitted under section 505(b)(2) of the Act is referred to as a 505(b)(2) application and an application submitted under section 505(j) of the Act is referred to as an abbreviated new drug application (ANDA).

⁵ Section 505(q)(1)(E) provides that FDA may issue guidance to describe the factors that will be used to determine whether a petition is submitted with the primary purpose of delaying the approval of an application. This guidance does not address the factors under section 505(q)(1)(E). Any guidance issued pursuant to section 505(q)(1)(E) will be issued separately from this guidance. FDA also is considering issuing regulations through notice and comment rulemaking to further implement section 505(q).

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36 FDA's guidance documents, including this guidance, do not establish legally enforceable
37 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
38 be viewed only as recommendations, unless specific regulatory or statutory requirements are
39 cited. The use of the word *should* in Agency guidances means that something is suggested or
40 recommended, but not required.

41

42

II. BACKGROUND

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45 FDAAA was enacted on September 27, 2007. Section 914 of Title IX of FDAAA took effect on
46 the date of enactment and amended section 505 of the Act by adding a new subsection (q).
47 Section 505(q) applies to certain petitions that request that FDA take any form of action related
48 to a pending ANDA or 505(b)(2) application and governs the manner in which these petitions are
49 treated. The provisions of section 505(q) are described in greater detail below.

50

A. Scope of Section 505(q)

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53 Section 505(q)(1)(A), together with section 505(q)(5), describes the general scope of section
54 505(q). Section 505(q)(1)(A) provides:

55

56 The Secretary shall not delay approval of a pending application submitted under
57 subsection (b)(2) or (j) because of any request to take any form of action relating to the
58 application, either before or during consideration of the request, unless—

59

- 60 (i) the request is in writing and is a petition submitted to the Secretary pursuant
61 to section 10.30 or 10.35 of title 21, Code of Federal Regulations (or any
62 successor regulations); and
63 (ii) the Secretary determines, upon reviewing the petition, that a delay is
64 necessary to protect the public health.

65

66 In section 505(q)(5), the term *application* is defined as an application submitted under section
67 505(b)(2) or 505(j) of the Act and the term *petition* is defined as a request described in
68 505(q)(1)(A)(i).

69

B. Determination of Delay

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72 If FDA determines that a delay of approval of an ANDA or 505(b)(2) application is necessary to
73 protect the public health, FDA is required to provide to the applicant not later than 30 days after
74 making the determination:

75

- 76 1. notification that the determination has been made,
77 2. if applicable, any clarification or additional data that the applicant should submit to
78 the petition docket to allow FDA to review the petition promptly, and
79 3. a brief summary of the specific substantive issues raised in the petition which form
80 the basis of the determination.⁶

⁶ Section 505(q)(1)(B).

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82 At FDA’s discretion, the information is to be conveyed by either a document or a meeting with
83 the applicant.⁷ The information conveyed as part of the notification is to be considered part of
84 the application and subject to the disclosure requirements applicable to information in such
85 application.⁸

C. Certification and Verification

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87
88 Under section 505(q)(1)(H), FDA may not consider a petition for review unless the petition is in
89 writing and signed and contains a certification that is specified in that section. In addition, FDA
90 may not accept for review any supplemental information or comments on a petition unless the
91 submission is in writing and signed and contains a specific verification.⁹

D. Final Agency Action

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95 Section 505(q)(1)(F) governs the timeframe for final Agency action on a petition. Under this
96 provision, FDA shall take final Agency action on a petition not later than 180 days after the date
97 on which the petition is submitted. The 180-day period is not to be extended for any reason,
98 including any determination made under section 505(q)(1)(A) regarding delay of approval of an
99 application, the submission of comments or supplemental information, or the consent of the
100 petitioner.

101
102 FDA may deny a petition at any point if the Agency determines that a petition or a supplement to
103 the petition was submitted with the primary purpose of delaying the approval of an application
104 and the petition does not on its face raise valid scientific or regulatory issues.¹⁰ FDA may issue
105 guidance to describe the factors that will be used to determine whether a petition is submitted
106 with the primary purpose of delaying the approval of an application.¹¹

E. Judicial Review

107
108 Section 505(q)(2) governs judicial review of final Agency action. Under section 505(q)(2)(A),
109 FDA shall be considered to have taken final Agency action on a petition if FDA makes a final
110 decision within the meaning of 21 CFR 10.45(d) during the 180-day period or the 180-day period
111 expires without FDA having made a final decision. Under section 505(q)(2)(B), if a civil action
112 is filed against the Secretary with respect to any issues raised in the petition before final Agency
113 action, a court shall dismiss the action without prejudice for failure to exhaust administrative
114 remedies. Section 505(q)(2)(C) describes the information to be included in the administrative
115 record.
116
117
118
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⁷ Section 505(q)(1)(C).

⁸ Section 505(q)(1)(D).

⁹ Section 505(q)(1)(I).

¹⁰ Section 505(q)(1)(E).

¹¹ Section 505(q)(1)(E). As noted in footnote 5, any guidance issued pursuant to section 505(q)(1)(E) will be issued separately from this guidance.

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F. Exceptions and Reporting

Section 505(q)(4) exempts certain categories of petitions from the provisions of section 505(q) — in particular, petitions relating to 180-day generic drug exclusivity and petitions from a 505(b)(2) or ANDA applicant regarding FDA actions with respect to that application. Section 505(q)(3) and section 914(b) of FDAAA also provide for certain reporting requirements from FDA to Congress.

III. DISCUSSION

As described in section II of this guidance, the provisions of section 505(q) addressing the treatment of petitions apply only to certain petitions. These provisions include, for example, the requirements that approval of an ANDA or 505(b)(2) application not be delayed by a petition absent an Agency determination that a delay is necessary to protect the public health, the provisions requiring final Agency action on the petition within 180 days of submission, and the provisions requiring a certification or a verification.

We describe below how we determine:

- if the provisions of section 505(q) apply to a particular petition
- if a petition would delay approval of a pending ANDA or 505(b)(2) application

We also describe how we interpret:

- section 505(q)(1)(H) requiring that a petition include a certification
- section 505(q)(1)(I) requiring that supplemental information or comments on a petition include a verification

We also describe the relationship between the review of petitions under section 505(q) and the review of ANDAs and 505(b)(2) applications for which the Agency has not yet made a final decision on approvability.

A. How Does FDA Determine if Section 505(q) Applies to a Particular Petition?

We interpret section 505(q) to apply to a petition only if the petition meets all of the following criteria:

- The petition is submitted to FDA on or after September 27, 2007.
- The petition is submitted in writing and pursuant to 21 CFR 10.30 or 10.35.
- An ANDA or 505(b)(2) application is pending at the time the petition is submitted to FDA.
- The petitioner requests an action that could delay approval of a pending ANDA or 505(b)(2) application.
- The petition does not fall within any of the exceptions described in section 505(q)(4).

We discuss each criterion in greater detail below.

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1. Petition Submitted on or after September 27, 2007

Because section 914 of FDAAA became effective on September 27, 2007, we believe that the provisions of section 505(q) only apply to petitions that are submitted on or after September 27, 2007. We do not believe that section 505(q) applies to any petitions that were submitted before September 27, 2007, because section 505(q) does not state that it applies retroactively to petitions submitted before the effective date. In addition, such an interpretation might impose a 180-day deadline for responding to a petition after the 180 days have already expired.

Even if section 505(q) were interpreted to retroactively apply to pre-September 27, 2007, petitions, FDA would not be able to review any petition submitted before September 27, 2007, because those petitions would not contain the required certification and, as explained in section III.C of this guidance, the statute does not permit a petitioner to cure the deficiency by supplementing a pre-September 27, 2007, petition to add the certification to the petition.

2. Petition Submitted in Writing and Pursuant to § 10.30 or 10.35

Under section 505(q) of the Act, a petition must be submitted in writing and pursuant to § 10.30 or 10.35. Section 10.30 of our regulations describes FDA’s general requirements for submitting a citizen petition, and § 10.35 describes our requirements for submitting a request for administrative stay of action. If these criteria are not met, we will not consider section 505(q) to apply to the petition.

We note that communications with the Agency regarding any issues intended to delay the approval of an ANDA or 505(b)(2) application (regardless of whether the communications are considered to be petitions subject to section 505(q)) are appropriately submitted through the petition process pursuant to § 10.30 or 10.35 rather than as correspondence to the NDA, ANDA, or 505(b)(2) application or another process. Similarly, any communications regarding a citizen petition should be filed as comments in the appropriate docket, not to the NDA, ANDA, or 505(b)(2) application.

We also remind persons that they may not cross-reference or rely upon information that is not included in the petition. Under §§ 10.30(b) and 10.35(b), petitions must be submitted in accordance with 21 CFR 10.20. Section 10.20(c) requires that “[i]nformation referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.” In addition, the certification required for petitions subject to section 505(q) (described in section III.C of this guidance) and the certification required for citizen petitions under § 10.30(b) require the petitioner to certify that “this petition includes all information and views upon which the petition relies.” A petition therefore is required to include all information referred to or relied upon by the petitioner. In addition, the petition should contain all information, both favorable and unfavorable, regarding the petitioner’s claims.

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3. *ANDA or 505(b)(2) Application Is Pending at the Time the Petition Is Submitted*

Section 505(q)(1)(A) describes the scope of section 505(q) (see section II of this guidance). Section 505(q)(1)(A) specifically references pending applications and contemplates the possibility that approval could be delayed by issues raised in a petition. Therefore, we interpret section 505(q) to apply only to petitions for which, at the time the petition is submitted, at least one ANDA or 505(b)(2) application related to the subject matter of the petition is pending.¹² If there is no related ANDA or 505(b)(2) application pending at the time that the petition is submitted, then we will not consider the provisions of section 505(q) to apply to the petition. We believe this interpretation is appropriate because if no related ANDA or 505(b)(2) application is pending at the time that a petition is submitted, the references in section 505(q)(1)(A) to a pending application and delay of approval by a petition would be inapplicable.

We also believe our interpretation is appropriate to ensure the fair and orderly implementation of section 505(q). Because application of the provisions of section 505(q) flows from a determination that a petition is within the scope of section 505(q), the evaluation of whether a related ANDA or 505(b)(2) application is pending needs to be made at the time that the petition is submitted. If we were to take a “rolling” evaluation approach, the status of the petition could change at any time from one that is not subject to section 505(q) to one that is subject to section 505(q) should a related ANDA or 505(b)(2) application be submitted before we have taken final Agency action on the petition. Such a change in the status of the petition would disrupt the orderly application of the provisions of section 505(q) and also could prejudice petitioners and commenters.

For example, as described in sections III.C and D of this guidance, to be reviewed by FDA, any petition subject to section 505(q) must include a certification and any comments to a petition subject to section 505(q) must include a verification. If, after submission, a petition’s status were converted from not being subject to section 505(q) to being subject to section 505(q), a petitioner who did not include a certification in the petition and/or commenter who did not include a verification in the comments would be prejudiced because the petition or the comments would not be eligible for review by FDA.

For these reasons, we interpret section 505(q) to apply only to petitions for which, at the time the petition is submitted, at least one ANDA or 505(b)(2) application related to the subject matter of the petition is pending. We recognize that petitioners may not be aware of the existence of a pending application. Therefore, we encourage all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application to include the certification required in section 505(q)(1)(H).

¹² Although the existence of a pending application generally is not made public by FDA, a potential petitioner may be aware of the existence of a pending ANDA or 505(b)(2) application, because of (1) a paragraph IV patent notification, from the applicant to the new drug application (NDA) holder and the patent owner, stating that the application has been submitted and explaining the factual and legal bases for the applicant’s opinion that the patent is invalid or not infringed (see section 505(b)(2)(B) and (j)(2)(B) of the Act), (2) a public announcement by the applicant disclosing the submission of the application, or (3) the tentative approval of an ANDA or 505(b)(2) application made public by FDA or the applicant. In addition, FDA’s Web site identifies drug products for which the Agency has received an ANDA with a paragraph IV certification.

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247 4. *Petition Requests an Action That Could Delay Approval of a Pending ANDA or*
248 *505(b)(2) Application*
249

250 As noted, section 505(q)(1)(A) contemplates the possibility that approval of a pending ANDA or
251 505(b)(2) application could be delayed by issues raised in the petition.¹³ Therefore, we interpret
252 section 505(q) to apply only to petitions that request an action that could delay approval of a
253 pending ANDA or 505(b)(2) application. If the action requested by the petition could not delay
254 approval of the application under any reasonable theory, we will not consider the provisions of
255 section 505(q) to apply to the petition.
256

257 5. *Petition Does Not Fall Within Any of the Exceptions Described in Section*
258 *505(q)(4)*
259

260 Section 505(q)(4) provides that section 505(q) will not apply to any petitions that:
261

- 262 1. relate solely to the timing of approval of an application pursuant to the 180-day
263 exclusivity provision at section 505(j)(5)(B)(iv) of the Act, or
- 264 2. are from the sponsor of the ANDA or 505(b)(2) application and seek only to have FDA
265 take or refrain from taking any action with respect to that application.
266

267 If either of these exceptions applies, we will not consider the provisions of section 505(q) to
268 apply to the petition.
269

270 **B. How Does FDA Determine if a Petition Would Delay Approval of an ANDA or**
271 **505(b)(2) Application?**
272

273 Under section 505(q)(1)(A), FDA shall not delay approval of an ANDA or 505(b)(2) application
274 because of a petition unless the Agency determines that a delay is necessary to protect the public
275 health. To implement this provision, first we determine if the provisions of section 505(q) apply
276 to the petition based on the criteria described in section III.A of this guidance. If the provisions
277 apply, we then determine if the petition may be summarily denied as described in section
278 505(q)(1)(E) (which allows denial of a petition that was submitted with the primary purpose of
279 delaying approval of an application and does not on its face raise valid scientific or regulatory
280 issues).
281

282 If we do not find that the petition may be summarily denied, we will determine if the petition
283 would be the cause of a delay in an approval of an ANDA or 505(b)(2) application by using a *but*
284 *for* test. In other words, would the ANDA or 505(b)(2) application be ready for approval but for
285 the issues raised by the petition?
286

¹³ We note that there are means other than submission of a petition by which interested persons can express their views on issues related to bioequivalence. FDA has been posting draft product-specific bioequivalence recommendations on its Web site at <http://www.fda.gov/cder/guidance/bioequivalence/default.htm> and announcing in a *Federal Register* notice the availability of these recommendations and the opportunity for the public to consider and comment on the recommendations. We encourage interested persons to submit any comments related to bioequivalence issues in response to a *Federal Register* notice announcing the recommendations.

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- If, regardless of the petition, the ANDA or 505(b)(2) application would not be ready for approval, then section 505(q)(1)(A) would not be implicated.¹⁴
 - If the ANDA or 505(b)(2) application would be ready for approval but for the petition, then we would next determine if a delay of approval is necessary to protect the public health.

293

294 We determine if a delay of approval is necessary to protect the public health based on our

295 preliminary evaluation of the issues raised in the petition. The Agency considers the following:

296

297 If the application were approved before the Agency completed the substantive

298 review of the issues in the petition and, after further review, the Agency

299 concluded that the petitioner’s arguments against approval were meritorious,

300 could the presence on the market of drug products that did not meet the

301 requirements for approval negatively affect the public health?

302

303 If, after undertaking this analysis, we conclude that the public health could be negatively

304 affected, the Agency will conclude that a delay “is necessary to protect the public health” and

305 will delay approval of the pending application. Issues that could implicate the public health

306 include, for example, (1) whether a proposed generic drug product is bioequivalent to the

307 reference listed drug or (2) whether an indication can be safely omitted from the labeling because

308 that indication is protected by a patent.

309

310 If we determine that a delay is necessary, we will notify the applicant as required by section

311 505(q)(1)(B) and (C) of the Act. Under these provisions, we are required to provide the

312 following information to the applicant not later than 30 days after making the determination:

- 313
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- 317
- Notification that the determination has been made
 - If applicable, any clarification or additional data that the applicant should submit to the petition docket to allow FDA to review the petition promptly
 - A brief summary of the specific substantive issues raised in the petition which form the basis of the determination
- 318

319 At our discretion, we will convey this information to the applicant by either a letter or a meeting

320 with the applicant.¹⁵ As provided in section 505(q)(1)(D), we will consider the information

321 conveyed in the notification to be part of the application and subject to the disclosure

322 requirements applicable to information in such application. We do not intend to notify the

323 petitioner if a determination has been made that a delay in approval of an application is necessary

324 to protect the public health because the provisions of section 505(q) do not require such a

325 notification to the petitioner.

326

327 If we determine that a delay of approval is not necessary to protect the public health, we will

328 proceed with approving the application.

¹⁴ We note, however, that a petition would still be subject to section 505(q) as long as a relevant application is pending at the time the petition is submitted.

¹⁵ See section 505(q)(1)(C).

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C. How Does FDA Apply the Certification Requirements in Section 505(q)(1)(H)?

Section 505(q)(1)(H) of the Act provides that FDA shall not consider a petition for review unless the petition is in writing and signed and contains the following certification:

I certify that, to my best knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. 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: _____ [in the blank space, provide the date on which such information first became known to such party]. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: _____ [in the blank space, provide the names of such persons or organizations]. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

This certification includes statements in addition to those described under § 10.30(b) for the certification in citizen petitions.

We apply section 505(q)(1)(H) to require that all petitions that fall within the scope of section 505(q) be in writing and signed, and contain the complete 505(q) certification to be considered for review by FDA. If, based on the criteria described in section II.A of this guidance, section 505(q) applies to the petition, but the petition is not in writing or signed, or does not contain the complete certification, we will not review the petition.

We also apply section 505(q)(1)(H) to require that the certification be included in the original petition. Section 505(q)(1)(H) refers to the “petition” as the subject document that must contain the certification. Because sections 505(q)(1)(E) and 505(q)(1)(I) distinguish between petitions and supplements to petitions,¹⁶ the reference to a petition in section 505(q)(1)(H) refers only to the original petition and not to a supplement. Therefore, if a petition is missing the complete certification, we will not permit a petitioner to cure the deficiency by submitting a supplement to add the certification to the petition.

If a petitioner has submitted a petition that is missing the required certification but is otherwise within the scope of section 505(q) and the petitioner would like FDA to review the petition, the petitioner should (1) submit a letter withdrawing the deficient petition pursuant to § 10.30(g) and (2) submit a new petition that contains the certification. In this case, the provisions of section 505(q) governing the treatment of petitions will apply only to the new petition that includes the required certification because we cannot review the deficient petition under section 505(q)(1)(H).

¹⁶ Section 505(q)(1)(E) states that if FDA determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying approval of an application, the Agency may deny the petition at any point. Section 505(q)(1)(I) requires that supplemental information include a verification as described in section III.D of this guidance.

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373 In particular, we consider the 180-day timeframe for FDA to respond to the petition to begin
374 from the date of submission of the new, complete petition and not the original, deficient petition.
375

376 Because FDA will not review a petition that is subject to section 505(q) but is missing the
377 required certification, we strongly encourage all petitioners raising issues that could delay the
378 approval of a possible ANDA or 505(b)(2) application to include the certification in their
379 petitions to ensure FDA consideration. Although we may contact a petitioner to notify him or
380 her of a missing or deficient certification, we note that it is the responsibility of the petitioner to
381 ensure that its petition complies with the applicable requirements of section 505(q), as well as all
382 other applicable statutory and regulatory requirements.
383

D. How Does FDA Apply the Verification Requirements in Section 505(q)(1)(I)?

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385
386 Section 505(q)(1)(I) provides that FDA shall not accept for review any supplemental information
387 or comments on a petition unless the supplemental information or comments are in writing,
388 signed, and contain the following verification:
389

390 I certify that, to my best knowledge and belief: (a) I have not intentionally delayed
391 submission of this document or its contents; and (b) the information upon which I have
392 based the action requested herein first became known to me on or about _____ [in
393 the blank space, provide the date on which such information first became known to such
394 party]. If I received or expect to receive payments, including cash and other forms of
395 consideration, to file this information or its contents, I received or expect to receive those
396 payments from the following persons or organizations: _____ [in the blank space,
397 provide the names of such persons or organizations]. I verify under penalty of perjury
398 that the foregoing is true and correct as of the date of the submission of this petition.
399

400 Section 505(q)(1)(I) applies to any supplemental information or comments that are submitted to
401 a petition that is subject to section 505(q). If any such supplemental information or comments do
402 not include the required verification, FDA will not review the submission.
403

404 If a petitioner or commenter has submitted supplemental information or comments without the
405 required verification or with an incomplete verification and the petitioner or commenter would
406 like FDA to review the submission, the petitioner or commenter should resubmit the
407 supplemental information or comments with the required verification to FDA.
408

409 For petitions that are subject to section 505(q), because FDA will not review any supplemental
410 information or comments that are missing the required verification, we strongly encourage all
411 petitioners or commenters to include the verification in their supplemental information or
412 comments to a petition that includes the 505(q) certification to ensure FDA consideration. We
413 will not notify petitioners and commenters of a missing or deficient verification. In some
414 instances, FDA receives numerous supplements and comments in a docket, and it would be
415 administratively burdensome to monitor all the dockets for 505(q) petitions and notify
416 commenters about the statutory requirement. It is the responsibility of petitioners and
417 commenters to ensure that their supplemental information or comments comply with the
418 applicable requirements of section 505(q), as well as all other applicable statutory and regulatory
419 requirements.
420

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421
422 **E. What Is the Relationship Between the Review of Petitions Under Section 505(q) and**
423 **the Review of ANDAs and 505(b)(2) Applications for Which the Agency Has Not**
424 **Yet Made a Final Decision on Approvability?**
425

426 A petition may request that FDA take an action related to a specific aspect of a pending ANDA
427 or 505(b)(2) application for which the Agency will not have made a final decision regarding
428 approvability by the date that the petition response is due. As described in section II.D., section
429 505(q)(1)(F) requires FDA to take final Agency action on a petition within 180 days of
430 submission. The review of applications that may be affected by the petition is governed by a
431 separate review process, which will not necessarily be completed by the date the petition
432 response is due. If a petition requests that the Agency take an action related to a specific aspect
433 of a pending application, we will consider the review status of the affected application(s) in
434 determining whether it would be appropriate for the Agency to respond to the request to take the
435 action requested in the petition within the 180-day timeframe.

436
437 The provisions in section 505 of the Act and FDA's regulations at 21 CFR part 314 establish
438 certain procedures by which the Agency reviews an NDA or ANDA and notifies an applicant if
439 it determines that an application is approved (§ 314.105) or may not be approved (section 505(c)
440 and 505(j); §§ 314.125 and 314.127), or identifies the deficiencies in the application and the
441 steps an applicant may take to respond to the deficiencies (§ 314.110). In addition, the statute
442 and regulations describe a specific process through which an applicant whose application the
443 Agency has found not to meet the requirements for approval may challenge the Agency's
444 determination (section 505(c)(1)(B) and (d), 505(j)(5)(E); § 314.200). Under this process, the
445 Agency must give the applicant notice of an opportunity for a hearing on whether the application
446 is approvable, with a specific timeframe and process should the applicant request such a hearing.
447 These procedures ensure that applicants have an adequate opportunity to challenge a finding by
448 the Agency that a product does not meet the requirements for approval.

449
450 By contrast, responses to citizen petitions, including petitions subject to section 505(q),
451 constitute final Agency action and are subject to immediate review by the courts. They therefore
452 carry with them none of the procedural rights for the affected applicants that attach to a decision
453 to deny approval of an application. If we were to respond substantively a petitioner's request
454 regarding the approvability of a certain aspect of a pending application before we have taken a
455 final action on the approvability of the application as a whole, such response could interfere with
456 the statutory and regulatory scheme governing the review of applications and related procedural
457 rights of applicants.¹⁷ There is no evidence that in enacting section 505(q), Congress intended to
458 limit applicants' procedural rights by requiring that the Agency make decisions that constitute
459 final Agency action on the approvability of specific aspects of a pending application (e.g., the
460 acceptability of a proposed trade name, specific claims proposed in a drug product's labeling) on
461 a piecemeal basis outside of the process established under the Act and regulations.¹⁸

¹⁷ We also note that under applicable statutory and regulatory provisions, we are generally prohibited from disclosing information regarding applications that have not yet been approved. Depending upon the nature and specificity of a petition, these limitations on disclosure also may circumscribe the Agency's ability to respond substantively to issues raised in a petition that affect a pending application.

¹⁸ In the past, we have responded to requests related to general standards for approval (e.g., bioequivalence criteria for generic drug products or the appropriateness of omitting certain protected information from proposed drug

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Therefore, we do not interpret section 505(q) to require a substantive final Agency decision within 180 days on the approvability of a specific aspect of a pending application when a final decision on the approvability of the application as a whole has not yet been made and when to render such a decision could deprive an applicant of procedural rights established by statute and regulations. In such a situation, we would expect to deny a petition without comment on the substantive approval issue.

product labeling) that may pertain to one or more pending drug applications, without commenting on the approvability of any particular aspect of a specific pending application. We distinguish our approach of responding to petitions that involve general policies or standards for approval of a drug application from our approach described above, which applies to petitions that involve narrow issues of approvability of a specific aspect or aspects of a pending application. We will continue to evaluate each citizen petition on a case-by-case basis with respect to the appropriateness of responding to the petitioner’s requests vis-à-vis any pending applications.