

(vi) The submission does not contain a reference list of supporting information, such as published literature, unpublished information, abstracts and case reports, and a copy of the supporting information.

(vii) The submission includes data or information relevant for making a GRASE determination marked as confidential without a statement that the information may be released to the public.

(viii) The submission does not contain a complete environmental assessment under § 25.40 of this chapter or fails to provide sufficient information to establish that the requested action is subject to categorical exclusion under § 25.30 or § 25.31 of this chapter.

(ix) The submission does not contain a statement for each nonclinical laboratory study that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if it was not conducted in compliance with part 58 of this chapter, a brief statement of the reason for the noncompliance.

(x) The submission does not contain a statement for each clinical investigation involving human subjects that the investigation was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to those regulations, and that the investigation was conducted in compliance with the informed consent regulations in part 50 of this chapter.

(xi) The submission does not include financial certification or disclosure statements, or both, as required by part 54 of this chapter, accompanying any clinical data submitted.

(k) *Withdrawal of consideration.* (1) Notwithstanding paragraph (g) of this section, FDA may withdraw consideration of a TEA submission or a safety and effectiveness data submission if:

(i) The person that submitted the submission requests that its submission be withdrawn from consideration; or

(ii) FDA deems the submission to be withdrawn from consideration due to the submitter's failure to respond to the communications from FDA.

(2) Before FDA deems a submission withdrawn under paragraph (k)(1)(ii) of

this section, FDA will notify the person that submitted the submission. If, within 90 days from the date of the notice from FDA, the submitter requests that FDA not withdraw consideration of the submission, FDA will not deem the submission to be withdrawn.

(3) If FDA withdraws consideration of a submission under paragraph (k)(1) of this section, FDA will post a notice of withdrawal to the docket, except in the case of a TEA submission that is withdrawn from consideration before issuance of a notice of eligibility, in which case, the notice of withdrawal will only be provided to the sponsor. Information that has been posted to the public docket for the condition at the time of the withdrawal (such as a notice of eligibility or a safety and effectiveness data submission that has been accepted for filing and posted to the docket) will remain in the public docket. If the condition has been found eligible through issuance of a notice of eligibility, the condition remains eligible for consideration and the sponsor or any interested person can pursue consideration of the condition in the future by submitting a new safety and effectiveness data submission.

(4) If FDA withdraws consideration of a submission under paragraph (k)(1) of this section, the timelines under § 330.15(c) will no longer apply as of the date of withdrawal, and the submission will not be included in the metrics under § 330.15(b).

[67 FR 3074, Jan. 23, 2002, as amended at 81 FR 84475, Nov. 23, 2016; 88 FR 45066, July 14, 2023]

§ 330.15 Timelines for FDA review and action on time and extent applications and safety and effectiveness data submissions.

(a) *Applicability.* This section applies to the review of a condition in a time and extent application (TEA) submitted under § 330.14 for consideration in the over-the-counter (OTC) drug monograph system. This section does not apply to:

(1) A sunscreen active ingredient or combination of sunscreen active ingredients, and other conditions for such ingredients; or

(2) A non-sunscreen active ingredient or combination of non-sunscreen active

ingredients, and other conditions for such ingredients submitted in a TEA under §330.14 before November 27, 2014, subject to section 586F(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act.

(b) *Metrics.* FDA will maintain and update annually, a publicly available posting of metrics for the review of TEAs and safety and effectiveness data submissions that are subject to the timelines in this section. The posting will contain the following information for tracking the extent to which the timelines set forth in paragraph (c) of this section were met during the previous calendar year.

(1) Number and percent of eligibility notices or ineligibility letters issued within 180 days of submission of a TEA;

(2) Number and percent of filing determinations issued within 90 days of submission of a safety and effectiveness data submission;

(3) If applicable, number and percent of feedback letters issued within 730 days from the date of filing;

(4) Number and percent of notices for proposed rulemaking issued within 1,095 days from the date of filing;

(5) Number and percent of final rules issued within 912 days of closing of the docket of the proposed rulemaking; and

(6) Total number of TEAs submitted under §330.14.

(c) *Timelines for FDA review and action.* FDA will review and take an action within the following timelines:

(1) Within 180 days of submission of a TEA under §330.14(c), FDA will issue a notice of eligibility or post to the docket a letter of ineligibility, in accordance with §330.14(d) and (e).

(2) Within 90 days of submission of a safety and effectiveness data submission, in accordance with §330.14(j), FDA will issue a filing determination. The date of filing begins the FDA timelines in paragraphs (c)(3) and (4) of this section.

(3) Within 730 days from the date of filing, if the condition is initially determined not to be GRASE for OTC use in the United States, FDA will inform the sponsor and other interested persons who have submitted data of its determination by feedback letter in accordance with §330.14(g)(4).

(4) Within 1,095 days from the date of filing of a safety and effectiveness data

submission, FDA will issue a notice of proposed rulemaking to either:

(i) Include the condition in an appropriate OTC monograph(s), either by amending an existing monograph(s) or establishing a new monograph(s), if necessary; or

(ii) Include the condition in §310.502 of this chapter.

(5) Within 912 days of the closing of the docket of the proposed rulemaking under paragraph (c)(4) of this section, FDA will issue a final rule.

[81 FR 84477, Nov. 23, 2016]

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

Subpart A—General Provisions

Sec.

331.1 Scope.

Subpart B—Active Ingredients

331.10 Antacid active ingredients.

331.11 Listing of specific active ingredients.

331.15 Combination with nonantacid active ingredients.

Subpart C—Testing Procedures

331.20 Determination of percent contribution of active ingredients.

331.21 Test Modifications.

Subpart D—Labeling

331.30 Labeling of antacid products.

331.80 Professional labeling.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 39 FR 19874, June 4, 1974, unless otherwise noted.

Subpart A—General Provisions

§ 331.1 Scope.

An over-the-counter antacid product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the following conditions and each of the general conditions established in §330.1 of this chapter.