must state that the new tobacco product has either:

(1) The same characteristics as the predicate tobacco product and the basis for this determination, or

(2) Different characteristics than the predicate tobacco product. Where an applicant states that its new tobacco product has different characteristics than the predicate tobacco product, the applicant must also include an explanation as to why a difference in any of the following characteristics do not cause the new product to raise different questions of public health: Product design (paragraph (a) of this section); heating source (paragraph (b) of this section); materials and ingredients (paragraph (c) of this section); and other features (paragraph (d) of this section). In addition, to demonstrate that a new tobacco product is substantially equivalent, an applicant must also explain why any differences in the manufacturing process between the new tobacco product and the predicate tobacco product would not change the characteristics of the new tobacco product such that the new tobacco product could raise different questions of public health (§ 1107.18(e)). Similarly, for smokeless tobacco products and tobacco products that contain fermented tobacco, an applicant must explain why any difference in stability between the new tobacco product and the predicate tobacco product does not cause the new tobacco product to raise different questions of public health (paragraph (f) of this section).

(h) *Comparison to original predicate tobacco product.* If the applicant is comparing the new tobacco product to a predicate tobacco product that FDA has previously found to be substantially equivalent, FDA may request that the applicant include information related to the original predicate tobacco product that was commercially marketed (other than for test marketing) in the United States as of February 15, 2007, even if that original predicate tobacco product is back several predicate tobacco products. FDA will request this information when necessary to ensure that any order the Agency issues finding the new tobacco product substantially equivalent complies with section 910(a)(2)(A)(i)(I) of the Federal Food, Drug, and Cosmetic Act. FDA may need to review the first SE Report that received a finding of substantial equivalence using the original predicate tobacco product as a predicate tobacco product in order to make this finding.

### § 1107.20 Amendments.

(a) Except as provided in paragraphs (b) and (c) of this section, the applicant may submit an amendment to an SE Report in accordance with subpart C of this part. If an applicant chose to submit a health information summary with its SE Report under § 1107.18(j)(1), the applicant must submit with the amendment a redacted copy of the amendment that excludes research subject identifiers and trade secret and confidential commercial information as defined in §§ 20.61 and 20.63 of this chapter.

(b) An applicant may not amend an SE Report to change the predicate tobacco product.

(c) An applicant may not amend an SE Report after FDA has closed the SE Report under § 1107.44 or it has been withdrawn under § 1107.22.

(d) In general, amendments will be reviewed in the next review cycle as described in § 1107.42.

### § 1107.22 Withdrawal by applicant.

(a) An applicant may at any time make a written request to withdraw an SE Report for which FDA has not issued an order. The withdrawal request must state:

(1) Whether the withdrawal is due to a health or safety concern related to the tobacco product;

(2) The submission tracking number; and

(3) The name of the new tobacco product that is the subject of the SE Report.

(b) An SE Report will be considered withdrawn when FDA issues a notice stating the SE Report has been withdrawn.

(c) The SE Report is an Agency record, even if withdrawn. FDA will retain the withdrawn SE Report under Federal Agency records schedules. The

availability of the withdrawn SE Report will be subject to FDA's public information regulations in part 20 of this chapter.

### § 1107.24 Change in ownership of an SE Report.

An applicant may transfer ownership of its SE Report. On or before the time of transfer, the new and former applicants are required to submit information to FDA as follows:

(a) The former applicant must sign and submit a notice to FDA that states that all of the former applicant's rights and responsibilities relating to the SE Report have been transferred to the new applicant. This notice must identify the name and address of the new applicant and the SE Report transferred.

(b) The new applicant must sign and submit a notice to FDA containing the following:

(1) The new applicant's commitment to agreements, promises, and conditions made by the former applicant and contained in the SE Report;

(2) The date that the change in ownership is effective;

(3) Either a statement that the new applicant has a complete copy of the SE Report and order (if applicable), including amendments and records that are required to be kept under §1107.58, or a request for a copy of the SE Report from FDA's files by submitting a request in accordance with part 20 of this chapter. In accordance with the Freedom of Information Act, FDA will provide a copy of the SE Report to the new applicant under the fee schedule in FDA's public information regulations in §20.45 of this chapter; and

(4) A certification that no modifications have been made to the new tobacco product since the SE Report was submitted to FDA.

## Subpart D—FDA Review

SOURCE: 86 FR 55275, Oct. 4, 2021, unless otherwise noted.

### § 1107.40 Communications between FDA and applicants.

(a) *General principles.* During the course of reviewing an SE Report, FDA may communicate with applicants about relevant matters, including scientific, medical, and procedural issues that arise during the review process. These communications may take the form of telephone conversations, letters, or emails, and will be documented in the SE Report in accordance with §10.65 of this chapter.

(b) *Meeting.* Meetings between FDA and applicants may be held to discuss scientific and other issues. Requests for meetings will be directed to the Office of Science, Center for Tobacco Products, and FDA will make every attempt to grant requests for meetings that involve important issues.

(c) *Acceptance of an SE Report for review.* After receiving an SE Report under §1107.18, FDA will either refuse to accept the SE Report for review or issue an acceptance for review letter.

(d) *Notification of deficiencies in an SE Report submitted under §1107.18.* FDA will make reasonable efforts to communicate to applicants the procedural, administrative, or scientific deficiencies found in an SE Report and any additional information and data needed for the Agency's review. The applicant must also provide additional comparison information under §1107.19 if requested by FDA.

(e) *Withdrawal of SE Report.* An SE Report will be considered withdrawn when FDA issues a notice stating that the SE Report has been withdrawn.

### § 1107.42 Review cycles.

(a) *Initial review cycle.* FDA intends to review the SE Report and either communicate with the applicant as described in §1107.40 or take an action under §1107.44 within 90 calendar days of FDA's receipt of the SE Report, or within 90 calendar days of determining that the predicate was found to be commercially marketed (other than for test marketing) in the United States as of February 15, 2007 (if applicable), whichever is later. This 90-day period is called the ''initial review cycle.''

(b) *Additional review cycles.* If FDA issues a deficiency notification under §1107.40(d) during the initial review cycle, FDA will stop reviewing the SE Report until it receives a response from the applicant or the timeframe specified in the notification of deficiencies for response has elapsed. If the