LATHAM&WATKINS

Client Alert Commentary

Latham & Watkins Healthcare & Life Sciences Practice

April 11, 2023 | Number 3097

FDA Publishes Proposed Rule for Tobacco Product Manufacturing Practice Requirements

The proposed rule, if finalized, would impose new manufacturing practice requirements on foreign and domestic manufacturers of finished and bulk tobacco products.

On March 10, 2023, the Food and Drug Administration (FDA or the Agency) published a long-anticipated proposed rule, "Requirements for Tobacco Product Manufacturing Practice," which proposes new requirements for the manufacture, preproduction design validation, packing, and storage of all finished or bulk tobacco products.[1]

If finalized, the proposed rule would codify these requirements in a new part 1120 of Title 21 of the Code of Federal Regulations.[2] The proposed rule is a step toward fulfilling FDA's obligation under the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) to promulgate regulations regarding current good manufacturing practice for tobacco products, or tobacco product manufacturing practice (TPMP) requirements.[3] FDA also announced an April 12, 2023 public hearing on the proposed rule[4] and a May 18, 2023 meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) to provide recommendations on TPMPs.[5]

The proposed rule and TPSAC meeting provide opportunities for stakeholders to comment on tobacco manufacturing practice requirements and the timeline for their implementation. TPSAC will consider comments received by May 11, 2023 during its May 18, 2023 meeting. Comments received after this deadline but prior to September 6, 2023 will not be considered by TPSAC but will become part of the public docket for the meeting. FDA has also established a September 6, 2023 deadline for comments to the proposed rule, for FDA to consider before any final rule is implemented.

Overview of the Proposed Rule

The proposed rule would apply manufacturing practice requirements to foreign and domestic manufacturers of finished or bulk tobacco products,[6] cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, electronic nicotine delivery systems (ENDS), e-liquids, pipe tobacco, cigars, hookah tobacco, nicotine gels, and dissolvable tobacco products, as well as their components or parts.[7] The proposed rule would apply to components or parts which meet the definition of "tobacco products" but would not apply to manufacturers of accessories of finished or bulk tobacco products.[8]

The proposed rule is based on a Quality Management System (QMS) approach akin to the Agency's approach to the regulation of medical device manufacturing in the Quality System Regulation (QSR). FDA

states that this approach aims to provide a framework that requires manufacturers "to establish and maintain procedures for various aspects of the manufacturing, preproduction design validation, packing, and storage processes, while allowing flexibility to establish procedures unique to the manufacturer's facilities and activities, and appropriate for a given tobacco product."[9] The proposed rule divides these requirements into the various subparts of proposed part 1120.

Unique identifiers and the other subparts are discussed in more detail below:

- **General Provisions (Subpart A).** Proposed Subpart A describes the scope of the proposed Part 1120 and contains definitions. Among other things, the proposed rule would define a "tobacco product manufacturer" to include specification developers, contract manufacturers, and re-packagers and re-labelers of tobacco products.[10]

- **Management System Requirements (Subpart B).** Proposed Subpart B contains requirements concerning organizational structure and personnel qualification, tobacco product complaint handling, and corrective and preventative actions (CAPAs). Specifically, proposed 21 C.F.R. § 1120.12 would require manufacturers to establish and maintain an organizational structure, and for management to establish processes and procedures, each to ensure that manufacturing operations meet applicable TPMP requirements.[11] The proposed rule would also impose requirements on personnel qualification and training.[12] Proposed Subpart B also would require manufacturers to establish and maintain certain procedures for the receipt, evaluation, and handling of tobacco product complaints, maintaining complaint records,[13] and for implementing CAPAs.[14]

- **Buildings, Facilities, and Equipment (Subpart C).** Under proposed Subpart C, manufacturers would need to take certain steps to ensure that their personnel, buildings, facilities, and equipment did not contaminate their tobacco products. Manufacturers would be required, for example, to establish and maintain procedures for the cleanliness, personal practices, and apparel of their personnel, and they would have to ensure that all equipment used in the manufacturing process is appropriately designed, constructed, and suitable for its intended use.[15] Further, manufacturers would be required to maintain and monitor environmental controls systems to verify that environmental controls are adequate and functioning properly.[16]

- **Design and Development Controls (Subpart D)**. Proposed Subpart D contains two sections: design and development activities and master manufacturing record. The design and development activities section would require finished and bulk tobacco product manufacturers to establish and maintain procedures to control the design and development of tobacco products.[17] These requirements would include developing a process for identification, analysis, and evaluation of known and reasonably foreseeable risks associated with a particular tobacco product. Under the proposed master manufacturing record section, manufacturers would be required to establish such a record for each finished and bulk tobacco product manufactured for distribution. The master manufacturing record would be required to include product specifications, manufacturing methods and production process procedures, and all packaging, labeling, and labels approved for use with the relevant tobacco product.[18]

- **Process Controls (Subpart E).** Proposed Subpart E contains requirements for purchasing controls, acceptance activities, production processes and controls, laboratory controls, production records, sampling, disposition of nonconforming tobacco products, returned tobacco products, and tobacco product reprocessing and rework. With respect to purchasing controls, manufacturers would be required to establish and maintain procedures to ensure that purchased or otherwise received

products and services related to the manufacture of a finished or bulk tobacco product are from qualified suppliers or vendors and conform to established specifications.[19]

Manufacturers would also be required to establish and maintain procedures for incoming, in-process, and/or final acceptance activities, as applicable, in order to ensure that tobacco products meet established specifications.[20] FDA states that such acceptance activities must include established acceptance criteria but methods could be accepted based on what is most suitable to the specific products and manufacturing processes.[21] Such methods could include inspections, such as visual inspections of incoming product; testing, such as laboratory testing for certain parameters; evaluations; and other verification activities, such as review of a supplier's certificate of analysis.[22]

Further, manufacturers would be required to establish and maintain procedures to control production processes, such as process specifications and validation.[23] These proposed requirements would include requirements to develop relevant acceptance criteria during the production process, such as time, temperature, or humidity process acceptance criteria to ensure that a product meets a product pH specification.[24] The proposed rule would require manufacturers to maintain production records for each batch of finished and bulk product.[25]

Laboratory controls requirements would include requirements that manufacturers demonstrate competence of any in-house or contract laboratory used to conduct activities under proposed 21 C.F.R. Part 1120, such as design and development activities, acceptance activities, process controls, and calibration of testing or measuring equipment.[26] Further, the proposed rule would require manufacturers to implement and maintain procedures for the identification, segregation, evaluation, and disposition of returned tobacco products. It also would require procedures for the control and disposition of nonconforming product, and for the preprocessing and reworking of tobacco products when appropriate.[27]

- **Packaging and Labeling (Subpart F)**. Proposed Subpart F would establish requirements concerning packaging and labeling activities, repackaging and relabeling, and warning plans. Under the proposed rule, manufacturers would be required to establish and maintain procedures to control packaging and labeling activities as well as repackaging and relabeling activities, and to maintain records of such activities.[28] Manufacturers would also be required to apply a "manufacturing code" to the product packaging and labeling, defined in relevant part, as "any distinctive sequence or combination" containing manufacturing date and batch number information.[29] Finally, the proposed rule would require finished tobacco product manufacturers to establish and maintain procedures to comply with the current, applicable warning plan requirements for tobacco product packaging.[30]

- **Handling, Storage, and Distribution (Subpart G)**. Proposed Subpart G would require finished and bulk tobacco product manufacturers to establish and maintain procedures to ensure that tobacco products are handled and stored under appropriate conditions to avoid nonconforming products and prevent mix-ups, deterioration, contamination, adulteration, and misbranding of tobacco products.[31] The proposed rule would also require finished and bulk tobacco product manufacturers to establish and maintain distribution procedures to ensure that all products are distributed to the initial consignee under appropriate conditions to avoid nonconforming product and prevent mix-ups, deterioration, contamination, adulteration, and misbranding of tobacco products.[32]

- **Recordkeeping and Document Controls (Subpart H)**. Proposed Subpart H would establish recordkeeping and document controls requirements for those written procedures, forms, work instructions, and similar documents established or maintained in connection with a TPMP

requirement. Among other things, such documents and records would need to be retained for at least four years from the date of distribution of the batch (or, in the case of documents and records associated with a batch of product, the expiration date of the product, if later).[33] Such documents would need to be maintained at the manufacturing establishment or otherwise be readily accessible to responsible individuals at the manufacturer, such that they could be promptly be made available to FDA.[34]

The proposed rule also provides a framework for manufacturers to seek a permanent or temporary exemption or variance from TPMP requirements. This framework would implement TCA Section 906(e)(2), which provides that any person subject to any TPMP requirement may petition FDA for a permanent or temporary exemption or variance from such requirement.[35] Proposed 21 C.F.R. § 1120.142 sets forth proposed form and content requirements for a petition for exemption or variance, and proposed 21 C.F.R. § 1120.146 provides that FDA may solicit additional information and consider a petition withdrawn if the petitioner does not timely respond.[36] Under the proposed rule, FDA would act on a petition within 60 days after "the date the complete submission was submitted to the FDA" or after the day the complete petition was referred to the TPSAC, if applicable.[37] The proposed rule also provides the opportunity for an informal hearing to challenge the agency's decision on a petition.

Timelines and Opportunities for Stakeholder Engagement

Stakeholders will have multiple opportunities to engage with FDA regarding the content of a final rule on TPMPs. On April 12, 2023, FDA will hold a public oral hearing titled "Proposed Requirements for Tobacco Product Manufacturing Practice."[38] On May 18, 2023, TPSAC will also hold a public meeting to discuss the proposed rule and provide stakeholders with an opportunity to provide comments.[39] Comments submitted by May 11, 2023 will be provided to the committee for consideration at the meeting. Further, the comment deadline for the proposed rule is September 6, 2023.

With respect to any final rule's implementation timeline, the TCA requires FDA to consider several factors in establishing the effective date of any regulations concerning TPMP requirements. Such factors include the differences in which different types of tobacco products have historically been manufactured, the financial resources of different manufacturers, and the state of their existing manufacturing facilities.[40] Further, FDA is required to "provide for a reasonable period for time for such manufacturers to conform" to such newly-promulgated TPMP requirements.[41] FDA has proposed that any final rule would not become effective until two years after being published in the Federal Register.[42]

Finally, under TCA Section 906(e)(1)(B)(v), FDA may not require small tobacco product manufacturers to comply with any TPMP regulations for at least four years following the regulation's effective date.[43] The proposed rule states that small tobacco product manufacturers of finished and bulk tobacco products would not be required to comply with the proposed TPMP regulations until four years after the final rule's effective date (i.e., six years after publication of a final rule in the Federal Register).

Conclusion

The proposed rule, if finalized, would impose new manufacturing practice requirements on foreign and domestic manufacturers of finished and bulk tobacco products. Industry and other stakeholders have the opportunity to meaningfully engage with FDA and TPSAC and to participate in the rulemaking process to help shape the content and timelines for implementation of a final rule regarding tobacco product manufacturing.

If you have questions about this Client Alert, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

J. Benneville (Ben) Haas
ben.haas@lw.com
+1.202.637.1084
Washington, D.C.

Nathan A. Beaton
nathan.beaton@lw.com
+1.202.637.1062
Washington, D.C.

You Might Also Be Interested In

FDA Finalizes Quality Recommendations for Cannabis in Clinical Investigations

Healthcare Coverage Developments on the Horizon for Emerging Technologies, Including Digital Technologies

FDA Omnibus Reform Act: Examining the Policy Changes

Endnotes

[1] Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15174 (Mar. 10, 2023) (to be codified at 21 C.F.R. pt. 1120) (hereinafter Tobacco Product Manufacturing Proposed Rule).

[2] *Id.* at 15175.

[3] 21 U.S.C. § 387f(e)(1)(A).

[4] Proposed Requirements for Tobacco Product Manufacturing Practice; Public Hearing; Request for Comments, 88 Fed. Reg. 14962 (Mar. 10, 2023).

[5] Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request 88 Fed. Reg. 14960 (Mar. 10, 2023).

[6] *Id.* The proposed rule, if finalized, would define a "finished tobacco product" as "a tobacco product, including any component or part, sealed in final packaging," and a "bulk tobacco product" as "any tobacco product that is not sealed in final packaging but is otherwise suitable for consumer use as a tobacco product," including "components or parts of tobacco products that are not sealed in final packaging but are otherwise suitable for consumer use as tobacco products." 88 Fed. Reg. at 15183-84.

[7] *Id.* at 15183.

[8] *Id.* at 15184.

[9] *Id.*

[10] *Id.* at 15175.

[11] *Id.* at 15191.

[12] *Id.*

[13] *Id.* at 15192.

[14] *Id.* at 15192, 15196.

[15] *Id.* at 15198.

[16] *Id.* at 15176.

[17] *Id.*

[18] *Id.* at 15202, 15208-15209.

[19] *Id.* at 15176.

[20] *Id.* at 15258.

[21] *See id.* at 15214.

[22] *See id.* at 15214.

[23] *Id.* at 15258-15259.

[24] *See id.* at 15217.

[25] *See id.* at 15176.

[26] *See id.* at 15220.

[27] *See id.* at 15176.

[28] *Id.* at 15176.

[29] *Id.*

[30] *Id.*

[31] *Id.* at 15176-15177.

[32] *Id.* at 15177.

[33] *Id.* at 15243.

[34] *Id.* at 15234.

[35] *See* 21 U.S.C. § 387f(e)(2).

[36] *Id.* at 15238.

[37] *See id.*

[38] Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15174 (Mar. 10, 2023).

[39] Proposed Requirements for Tobacco Products Manufacturing Practice; Tobacco Products Scientific Advisory Committee; Notice of Meeting; Request for Comments, 88 Fed. Reg. 14960 (Mar. 10, 2023).

[40] 21 U.S.C. § 387f(e)(1)(B)(iv)-(v).

[41] *Id.* § 387f(3)(1)(B)(iv).

[42] Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15174, 15239 (Mar. 10, 2023).

[43] 21 U.S.C. § 387f(e)(B)(v).