Case No. 22-2463

IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

GRIPUM LLC,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Refuse to Accept Letter
by the U.S. Food and Drug Administration

RESPONDENT'S MOTION TO DISMISS AND FOR EXTENSION OF TIME TO FILE THE CERTIFIED INDEX

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INTRODUCTION

The Family Smoking Prevention and Tobacco Control Act precludes the marketing of a "new tobacco product" without prior authorization from the U.S. Food and Drug Administration (FDA). 21 U.S.C. § 387j(a)(1)–(2). The required contents of an application to market a new tobacco product are governed by statute, *id.* § 387j(b)(1)(A)–(G), and FDA requires applicants to include certain information in specific forms so that the agency can efficiently process and review applications. 21 C.F.R. §§ 1105.10(a)(6)–(7), 1114.7(b)(1), 1114.17. FDA does not engage in substantive scientific review to determine whether a product meets the statutory criteria for marketing authorization until after determining that the application meets these preliminary requirements. During the substantive scientific review stage, FDA "shall deny" an application under § 387j(c) upon making any one of four enumerated findings. 21 U.S.C. § 387j(c)(2)(A)–(D). A "denial of an application under section 387j(c)" is reviewable in the courts of appeals. *Id.* § 387*l*(a)(1)(B).

Petitioner seeks review of FDA's refusal to accept its applications to market over 160 synthetic nicotine tobacco products. *See* Petition for Review, Exhibit A. FDA refused to accept petitioner's applications after

determining that they were administratively incomplete because they did not comply with formatting requirements and did not include certain required product-specific information. *See* Petition for Review, Exhibit A. Although petitioner asserts that this Court has jurisdiction under 21 U.S.C. § 387*l*(a)(1)(B), that provision only authorizes this Court to review a "denial of an application under section 387j(c)." Because FDA did not deny petitioner's applications under 21 U.S.C. § 387j(c), the petition should be dismissed for lack of jurisdiction. Petitioner's counsel has advised that petitioner intends to file an opposition to this motion.

Moreover, because this motion may result in the petition being dismissed, FDA requests an extension of time to file the certified index to the administrative record, which is currently due on September 27, 2022. FDA requests that the deadline be extended to 30 days after the Court rules on this motion. Petitioner consents to this request.

BACKGROUND

I. The Family Smoking Prevention and Tobacco Control Act

Finding that the use of tobacco products by youth "is a pediatric disease of considerable proportions," Congress, in the Family Smoking Prevention and Tobacco Control Act (TCA), gave FDA the authority to

regulate cigarettes and other tobacco products. TCA, Pub. L. No. 111-31, div. A, § 2(1), (15), 123 Stat. 1776, 1777 (2009). Congress recently expanded the TCA's definition of "tobacco product" to include products made with synthetic nicotine. *See* Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, Division P, Subtitle B. Among other provisions, the TCA prohibits the marketing of any new tobacco product (defined as a product not on the market as of February 15, 2007) unless and until FDA authorizes its marketing. 21 U.S.C. § 387j(a)(1)–(2). The statute requires that an application to market a new tobacco product include several components, such as information about the health risks of the new product, a full statement of the product's ingredients, and "such other information relevant to the subject matter of the application as the [FDA] may require." *Id.* at 387j(b)(1)(A)–(G).

After notice and comment, FDA established content and format requirements for applications to market new tobacco products. 21 C.F.R. § 1114.7(b); *see* Final Rule, Premarket Tobacco Product Applications and Recordkeeping Requirements, 85 Fed. Reg. 55300 (October 5, 2021). Among other requirements, applications must include certain product-specific information, 21 C.F.R. § 1114.7(c), and must provide that

information "using the form(s) that FDA provides." *Id.* § 1114.7(b)(1). FDA announced that it would produce a form, FDA Form 4057b, that applicants could use to submit groups of applications in a single submission. 85 Fed. Reg. 13840 (March 10, 2020). Applicants submitting what is referred to as a "bundled" application must include all necessary product-specific information for each application in the submission so that FDA can process and review the applications efficiently. *Id.* at 13840–41.

Upon receiving an application for premarket authorization, FDA "perform[s] an initial review of the [application] to determine whether it may be accepted for further review." 21 C.F.R. § 1114.27(a)(1). FDA refuses to accept applications that do not comply with the content and format requirements described above. *Id.* § 1114.27(a)(1)(i), (iv). If FDA refuses to accept an application, it issues a Refuse to Accept letter to the applicant, which identifies all deficiencies that prevented FDA from accepting the application. *Id.* § 1114.27(a)(3).

If FDA accepts an application, it then determines whether the application "contains sufficient information to permit substantive review," including information from published literature about the product's health risks. 21 C.F.R. § 1114.27(b). An application that meets those criteria is

then "filed." *Id.* Only once an application is "accepted" and "filed" does the agency engage in substantive scientific review to determine whether the product(s) meet the statutory criteria for marketing authorization. In the substantive scientific review stage, FDA "shall deny" an application under § 387j(c) upon making any one of four enumerated findings. 21 U.S.C. § 387j(c)(2)(A)–(D).

The TCA authorizes courts of appeals to review "a denial of an application under section 387j(c)." 21 U.S.C. § 387*l*(a)(1)(B). Specifically, no later than 30 days after a denial order, an adversely affected person "may file a petition for judicial review" of that order "with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business." *Id.*

II. Petitioner's Marketing Applications and FDA's Refuse to Accept Letter

On May 12, 2022, petitioner submitted a "bundled" application seeking marketing authorization for over 160 new tobacco products containing synthetic nicotine in liquid form. Petition for Review, Exhibit A. The products are used in flavored e-cigarettes that are particularly

attractive to youth and come in various flavors, including "Fruitx Melon" and "Primitive Grizzly." *Id.*

On July 19, 2022, FDA sent petitioner a Refuse to Accept letter, stating that petitioner's applications did not meet the regulatory requirements. FDA specified that the applications "were not submitted using FDA Form 4057b," a "required form[ ]," rendering the applications "administratively incomplete." Petition for Review, Exhibit A. FDA further explained that without the required FDA Form 4057b, the applications did not include certain product-specific information in the required format that is necessary to find the applications acceptable. *Id.* The Refuse to Accept letter did not state that the applications had been "denied," nor did it articulate a basis for denial under 21 U.S.C. § 387j(c)(2). *Id.*

Petitioner filed its petition with this Court on August 18, 2022, seeking review of FDA's refusal to accept its bundled applications. Petitioner asserts that this Court has jurisdiction "under 21 U.S.C. § 387*l*(a)(1)." Petition for Review.

ARGUMENT

The Court should dismiss the petition for lack of jurisdiction. Contrary to petitioner's assertion, 21 U.S.C. § 387*l*(a)(1) does not authorize this Court to review FDA's refusal to accept petitioner's applications because it was not a "denial of an application under section 387j(c)." 21 U.S.C. § 387*l*(a)(1)(B).

"Federal courts are courts of limited jurisdiction" and "possess only that power authorized by Constitution and statute." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). "The jurisdiction of the United States courts of appeals to directly review the action of administrative agencies is 'specifically conferred by legislation relating specifically to the determinations of such agencies made subject to review, and prescribing the manner and extent of review.'" *Alabama Tissue Center of University of Alabama Health Services Foundation, P.C. v. Sullivan*, 975 F.2d 373, 376 (7th Cir. 1992) (quoting *AFL v. NLRB*, 308 U.S. 401, 404 (1940)).

The provision cited in the petition, 21 U.S.C. § 387*l*(a), does not confer this Court with jurisdiction to review FDA's refusal to accept petitioner's applications. That provision authorizes courts of appeals to hear challenges to "a denial of an application under section 387j(c)." *Id.*

387*l*(a)(1)(B).[1] In contrast to a denial of an application, FDA issues a Refuse to Accept letter when an application is incomplete or does not conform to the basic administrative requirements and, therefore, is not ready for substantive review. 21 C.F.R. § 1114.27(a). Consistent with this distinction, FDA stated that petitioner's applications did not "meet the regulatory requirements to permit substantive review" and did not enumerate any of the four findings in § 387j(c)(2)(A) that would constitute the basis for a denial of petitioner's applications. Petition for Review, Exhibit A. Thus, FDA explained that it was "refusing to accept" the applications, not that it had denied them. *Id.* Accordingly, this case does not involve a marketing denial order under § 387j that is directly reviewable in a court of appeals under § 387*l*.

The Eleventh Circuit recently dismissed a similar petition for lack of jurisdiction under 21 U.S.C. § 387*l*. In *Purecigs, LLC v. FDA*, the petitioner sought review of FDA's refusal to file its applications, and the court of appeals posed a jurisdictional question to the parties, asking whether the

[1] The same section also authorizes courts of appeals to hear challenges to "the promulgation of a regulation under [21 U.S.C. § 387g] establishing, amending, or revoking a tobacco product standard." 21 U.S.C. § 387*l*(a)(1)(A). That provision is not at issue here.

Refuse to File letter constituted a "denial" of the application under 21 U.S.C. § 387*l*(a)(1). No. 22-10039 (11th Cir. Jan. 14, 2022) (jurisdictional question). The court invited the parties to identify any other statutory provision that would support jurisdiction for the court of appeals to review the refusal to file. *Id.* The court ultimately concluded that FDA's refusal to file the applications "did not deny Purecigs, LLC's premarket tobacco product applications and, therefore, the Refuse to File letter [was] not reviewable in th[e] Court [of Appeals] pursuant to 21 U.S.C. § 387*l*." Case No. 22-10039 (11th Cir. April 14, 2022) (order dismissing petition). Under parallel reasoning, this Court should dismiss the petition for lack of jurisdiction.

Because this motion may result in the dismissal of the petition, FDA requests an extension of time to file the certified index to the administrative record. FDA requests that the deadline be extended to 30 days after the Court issues a ruling on this motion. Under Federal Rule of Appellate Procedure 17(a), FDA must file the certified index within 40 days after being served with a petition for review, making the current deadline for the index September 27, 2022. If the Court grants this motion, the petition

will be dismissed and there will be no need to prepare and file a certified index. Petitioner consents to this extension request.

CONCLUSION

The Court should dismiss the petition for review for lack of jurisdiction and should extend the time to file the certified index to the administrative record until 30 days after the Court has ruled on this motion to dismiss.

September 14, 2022

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2022, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Oliver McDonald
OLIVER MCDONALD

CERTIFICATE OF COMPLIANCE

I hereby certify that this motion complies with the requirements of Federal Rule of Appellate Procedure 27(d)(1), since it complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6): it has been prepared in 14-point Book Antiqua, a proportionally spaced font.

I further certify that this motion complies with the type-volume limitation of Rule 27(d)(2) because it contains 1,788 words, excluding the accompanying documents authorized by Rule 27(a)(2)(B).

/s/ Oliver McDonald
OLIVER MCDONALD