COVINGTON & BURLING LLP

July 28, 2021

Memorandum

To: Megan Olsen, Council for Responsible Nutrition

From: Miriam Guggenheim

Re: FDA Warning Letters Not Final Agency Action

As requested, this memorandum addresses the legal status of FDA warning letters, such as the seven warning letters sent in July 2020 to marketers of products claiming to be hangover cures, in some of which FDA also asserted that the ingredient, N-acetyl-L-cysteine (NAC) is not a lawful dietary ingredient.

It is well established that FDA warning letters are not final agency action. They are neither formal expressions of FDA legal or policy decisions, nor enforcement actions that trigger legal consequences. FDA itself has repeatedly made this clear, in its own guidance to agency personnel and in numerous court submissions. Courts have universally agreed with the agency's position.

Because of their informal status, there is no mechanism for recipients who disagree with the letters to challenge them in court, and indeed, courts have rejected such challenges as not ripe for judicial review. This leaves recipients without an effective remedy or pathway to have their concerns about FDA's positions in such letters addressed. Recipients typically submit responses to warning letters to FDA, but the agency does not post these routinely, so the counterpoints are rarely heard. Meanwhile, warning letters are made public and occasionally highly publicized, leaving the erroneous impression that FDA's views expressed in the letters are final and binding, and that the matter is settled, when in fact this is not the case.

Below, we set forth FDA's policy and position regarding its own warning letters, as confirmed by numerous courts.

I. Legal Standard for Final Agency Actions

At the outset, we set forth the legal standard for final agency action. An administrative action is final if it satisfies two requirements. First, the action must mark the consummation of the agency's decision-making process.[1] Second, it must be an action by which rights or

[1] Bennett v. Spear, 520 U.S. 154, 177-78 (1997).

obligations have been determined, or from which legal consequences will flow.[2] Therefore, enforcement orders that are final agency actions will reflect the agency's final decision on a matter and will result in legal consequences for the recipient.

FDA has made clear, and courts agree, that the agency's warning letters are not final agency action, nor are they meant to be.

II. FDA Makes Clear that Warning Letters Are Informal, and Not Final Agency Actions

FDA's Regulatory Procedures Manual ("RPM"), which is a reference manual for agency personnel, defines and describes warning letters in a chapter entitled, "Advisory Actions." There, FDA explains that warning letters are intended "to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action. Warning Letters are issued to achieve voluntary compliance and to establish prior notice."[3] FDA states expressly:

> A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued.[4]

In describing the process for issuing warning letters, FDA states in the RPM that "Warning Letters can be issued at the discretion of the program office director without center [*i.e.*, Center for Food Safety and Applied Nutrition] concurrence,"[5] making clear that warning letters do not reflect a formal, coordinated expression of agency policy.

III. Courts Agree that FDA Warning Letters Are Not Final Agency Action, and Thus Not Reviewable

The FDA defended its position on the informality of its warning letters in *Holistic Candlers & Consumers Association v. Food & Drug Administration*.[6] In *Holistic Candlers*, manufacturers and distributors of ear candles sued after receiving warning letters from the FDA. The warning letters advised that ear candles are medical devices for which the companies had not received FDA's marketing approval or clearance. The letters further advised companies to

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[2] *Id.*

[3] U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL 4-1-1 at 3 (2021) (emphasis added).

[4] *Id.* at 4.

[5] *Id.* at 5.

[6] 664 F.3d 940 (D.C. Cir. 2012).

"take prompt action" and "cease marketing, promoting, and distributing ear candles" at the risk of regulatory action by the FDA.[7]

The D.C. Circuit held that FDA's warning letters did not constitute final agency action because they neither marked the consummation of the agency's decision-making process nor determined any legal rights or obligations.[8] First, FDA's RPM makes clear that FDA uses warning letters to give individuals or companies the opportunity to take voluntary action.[9] Second, the RPM gives FDA discretion to pursue enforcement after issuing a warning letter.[10] FDA does not purport to compel the agency or recipient to take action based on a warning letter.[11]

The court distinguished FDA warning letters from other letters that do constitute final agency action. In *Ciba-Geigy Corp. v. EPA*, the D.C. Circuit held that EPA's letters to manufacturers were final agency action because they expressed the agency's "unequivocal position" that it could require labeling changes on a pesticide without additional actions under a federal statute.[12] In contrast, the court noted, FDA stated in its brief that the agency may "only ban devices after going through a formal process that it has not undertaken here."[13]

The *Holistic Candlers* court further noted that statements about a warning letter, either on the agency's website or made orally by an FDA employee, are insufficient to transform an advisory warning letter into a final agency action.[14]

FDA defended this court's holding in a brief opposing review of the case by the Supreme Court. The agency noted that "most warning letters do not result in enforcement action."[15] In fiscal year 2011, for example, FDA issued 1,720 warning letters but pursued only 15 seizures and 16 injunctions.[16] Its position in the warning letters that the ear candlers violated the Act was "tentative [and] interlocutory [in] nature."[17] FDA confirmed that warning letters do not trigger

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[7] *Id.* at 942, 944.

[8] *Id.* at 943.

[9] *Id.* at 944.

[10] *Id.*

[11] *Id.*

[12] *Id.* at 945.

[13] *Id.* (quoting FDA Br. 19-20 (citing 21 U.S.C. § 360f)).

[14] *Id.*

[15] Brief for Respondents in Opposition, Holistic Candlers & Consumers Ass'n v. Food & Drug Admin., No. 11-1454 (Sept. 11, 2012), 2012 WL 3991471, at *10.

[16] *Id.*; U.S. FOOD & DRUG ADMIN., FDA ENFORCEMENT STATISTICS SUMMARY FISCAL YEAR 2011, https://www.fda.gov/media/83096/download.

[17] Brief for Respondents in Opposition, *supra* note 15.

legal consequences nor do they preclude further agency consideration or review.[18] The Supreme Court denied the ear candlers petition for review.

In sum, the D.C. Circuit concluded, and the Supreme Court refused to reconsider, that an FDA warning letter is not a final agency action that binds the agency or triggers legal consequences. Courts across the nation have come to a similar conclusion.[19]

IV. Implications of FDA Warning Letters

It is clear from FDA's own policy and multiple court decisions that FDA warning letters are merely informal, advisory statements urging the recipients to take voluntary action in accordance with the agency views expressed therein, though these are not official agency positions. Indeed, FDA has occasionally reversed course from the positions taken in warning letters, perhaps most notably with respect to a warning letter to KIND in 2015 requesting removal of the word "healthy" from KIND bar wrappers. After much back-and-forth correspondence in which KIND expressed its view that the agency's position was erroneous, FDA reversed its position taken in the warning letter, and agreed that KIND's use of the term "healthy" was not a nutrient content claim.

Such closure is rare in the context of FDA warning letters, however. More typically, a recipient who disagrees with the agency's position will engage in a few rounds of correspondence with FDA. If the company does not receive a further FDA response or objection to its last communication and the agency takes no actual enforcement action, this silence effectively reflects the agency's acquiescence to the company's position. But there is virtually no way for the company to communicate this outcome to the public, including consumers and retailers, and there is no avenue for vindication in the courts.

It is therefore important for stakeholders to understand that FDA warning letters are not final agency action or official statements of FDA policy. They are merely informal advisory letters, are subject to change, and rarely proceed to actual enforcement action.

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[18] *Id.* at *14.

[19] *See* Orton Motor, Inc. v. U.S. Dep't of Health & Human Servs., 884 F.3d 1205, 1215 (D.C. Cir. 2018) ("[T]his court has rejected the idea that an FDA warning letter itself is a consequence subject to judicial review."); Cody Labs., Inc. v. Sebelius, 446 Fed. Appx. 964, 969 (10th Cir. 2011) ("[E]very court to consider the question has held that an FDA warning letter does not constitute 'final agency action.'"); Dietary Supplemental Coal., Inc. v. Sullivan, 978 F.2d 560, 563 (9th Cir. 1992) (citing Biotics Research Corp. v. Heckler, 710 F.2d 1375, 1377 (9th Cir. 1983)); Hi-Tech Pharmaceuticals, Inc. v. Hahn, No. 19-1268 (D.D.C. June 29, 2020); Clinical Reference Lab., Inc. v. Sullivan, 791 F. Supp. 1499, 1503-504 (D. Kan. 1992).