ALERTS AND UPDATES

U.S. District Court for the District of Columbia Determines That FDA Warning Letters Are Not Final Agency Action

January 20, 2012

This reinforces the significance of entities that receive warning letters timely responding to the FDA to provide an appropriate record for a court to evaluate if the FDA takes enforcement action at a future date.

On January 3, 2012, the U.S. Court of Appeals for the District of Columbia Circuit in *Holistic Candlers and Consumers Association, et al. v. Food and Drug Administration*, No. 11-5118, determined that "warning letters" do not constitute "final agency action" subject to judicial review under the Administrative Procedures Act (APA).

In February 2010, the FDA issued "warning letters" to 15 manufacturers of ear candles. Ear candles are hollow tubes made of fabric soaked in beeswax or paraffin that a user places in his or her ear and sets on fire with an open flame. Manufacturers of ear candles have made claims that they mitigate or treat allergies, headaches, colds, flu and sinus congestion, and may also relieve vision disorders, depression or attention-deficit disorder. In the warning letters, the FDA stated that because of the claims, it appeared to the FDA that the ear candles were medical devices that had received neither pre-market approval nor clearance. After meeting with the FDA to discuss the warning letters, several manufacturers sued, contending that by issuing the warning letters, the FDA had determined that the ear candles are "unapproved medical devices." The FDA moved to dismiss, *inter alia*, on the basis that the warning letters were not final agency action. The appellate court agreed and stated "a warning letter communicates the agency's position on a matter" but is "informal and advisory" and does not commit FDA to taking any enforcement action. The court also determined that simply because an entity receiving a warning letter may, at some point, have to defend itself in an enforcement action based on the warning letter, it did not convert the warning letter into final agency action for purposes of suit under the APA. The court noted that the FDA had solicited a response from the manufacturers to the warning letters, but that the manufacturers had failed to do so and, instead, had filed this lawsuit. This reinforces the significance of entities that receive warning letters timely responding to the FDA to provide an appropriate record for a court to evaluate if the FDA takes enforcement action at a future date.

For Further Information

If you have any questions concerning this *Alert*, please contact Frederick R. Ball or any other member of the Pharmaceutical, Pharmacy and Food industry group or the attorney in the firm with whom you regularly work.