# Exhibit 11

# About Warning and Close-Out Letters

This page reviews the types of warning letters found on the FDA website.

## General FDA Warning Letters

When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter. The Warning Letter identifies the violation, such as poor manufacturing practices, problems with claims for what a product can do, or incorrect directions for use. The letter also makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform FDA of its plans for correction. FDA then checks to ensure that the company's corrections are adequate. Matters described in FDA warning letters may have been subject to subsequent interaction between FDA and the recipient of the letter that may have changed the regulatory status of the issues discussed in the letter.

- **View general FDA warning letters** (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

## Tobacco Retail Warning Letters

Compliance check inspections of tobacco retailers occur periodically, and are conducted to determine a retail establishment's compliance with the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and its regulations in effect, such as the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, found at Title 21 of the Code of Federal Regulations, Part 1140 (21 C.F.R. Part 1140). Tobacco products covered in compliance check inspections of tobacco retailers include cigarettes and smokeless tobacco.

All other Warning Letters issued by CTP for violations of the Federal Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act and its applicable regulations, can be found at FDA's main Warning Letter page at the Inspections, Compliance, Enforcement, and Criminal Investigations - Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters) page.

- **View tobacco retailer warning letters** (/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/tobacco-retailer-warning-letters)

## Drug Marketing and Advertising Warning Letters (and Untitled Letters to Pharmaceutical Companies)

These letters, sorted by month, only cover Division of Drug Marketing and Communications and Drug Warning Letters. Some of the letters have been redacted or edited to remove confidential information. "Cyber" letters are sent electronically via the Internet to web sites that offer to sell online prescription drugs that may be illegal. The letters warn these web site operators that they may be engaged in illegal activities and informs them of the laws that govern prescription drug sales.

- **View drug marketing and advertising Warning Letters** (/drugs/enforcement-activities-fda/warning-letters-and-notice-violation-letters-pharmaceutical-companies)

# Warning Letter Close-Out Letter Program (applies to letters issued on or after Sept. 1, 2009)

FDA may issue a Warning Letter close-out letter ("close-out letter") once the Agency has completed an evaluation of corrective actions undertaken by a firm in response to a Warning Letter. A close-out letter may issue when, based on FDA's evaluation, the firm has taken corrective action to address the violations contained in the Warning Letter. This procedure applies to Warning Letters issued on or after September 1, 2009.

A close-out letter will not be issued based on representations that some action will or has been taken. The corrective actions must actually have been made and verified by FDA. Usually, the standard for verifying that corrections have been implemented will be a follow-up inspection. If the Warning Letter contains violations that by their nature are not correctable, then no close-out letter will issue. Future FDA inspections and regulatory activities may further assess the adequacy and sustainability of these corrections. Should violations be observed during a subsequent inspection or through other means, enforcement action may be taken without further notice. The FDA office that issued the Warning Letter will issue the close-out letter, and that office may be contacted for information on a particular Warning Letter.

Any questions about close-out letter process in general can be addressed to the Division of Compliance Policy at WLCloseOutProcess@fda.hhs.gov (mailto:WLCloseOutProcess@fda.hhs.gov?subject=).