

FDA Adds Two New Substances to its Inventory of Effective FCS Notifications

October 8, 2015

The U.S. Food and Drug Administration (FDA) recently added two new substances to its Inventory of Effective Food Contact Substances (FCS) Notifications (<http://www.accessdata.fda.gov/scripts/fdcc/?set=FCN>). The newly listed substances and the manufacturers are listed below.

<p>1558 (http://www.accessdata.fda.gov/scripts/fdcc/?set=fcn&id=1558)</p>	<p>An aqueous mixture of hydrogen peroxide (HP; CAS Reg. No. 7722-84-1), percitric acid (CAS Reg. No. 127542-88-5), perlactic acid (CAS Reg. No. 75033-25-9), citric acid (CAS Reg. No. 77-92-9), and lactic acid (CAS Reg. No. 79-33-4), manufactured and characterized as further described in the notification.</p>	<p>Mantrose-Haeuser Co., Inc.</p>	<p>Aug 26, 2015</p>
<p>1557 (http://www.accessdata.fda.gov/scripts/fdcc/?set=fcn&id=1557)</p>	<p>Octadecyl 3,5-di-tert-butyl-4-hydroxyhydrocinnamate (CAS Reg. No. 2082-79-3). REPLACES FCN 1206</p>	<p>BASF Schweiz AG</p>	<p>Aug 26, 2015</p>

The Food and Drug Administration Modernization Act of 1997 amended the Federal Food, Drug, and Cosmetic Act to provide for the submission of food-contact notifications (FCNs). Under the FCN system, a manufacturer or supplier of a food-contact material may submit an FCN to FDA regarding the identity and use of a new food-contact substance (FCS), along with information supporting the conclusion that the substance is safe for the intended use.

If FDA does not object in writing within 120 days to the substance's use based on safety grounds, the submitter and its customers may market the substance. Once the notification becomes effective, FDA will add it to its Inventory of Effective FCS Notifications. For more background on submission of FCNs, please see the PackagingLaw.com article, "What is the Best Approach to Obtaining FDA Clearance for Food Contact Substances?" (http://www.packaginglaw.com/2601_.shtml)"