These responsibilities of the Secretary have been delegated to the Commissioner of Food and Drugs and redesignated to certain other FDA officials. These notices of filing are published in the Federal Register.

Under the Federal Register Act (44 U.S.C. chapter 15), the Administrative Committee of the Federal Register issues regulations regarding publishing documents in the Federal Register (1 CFR chapter I). Based on these governing regulations, the OFR classifies Agency documents published in the Federal Register in one of three categories: rules and regulations, proposed rules, and notices. The regulation establishing document types is 1 CFR 5.9. FDA’s section 409 and section 721 notices of filing have historically been published in the “Notices” section of the Federal Register. OFR recently informed FDA that, in their view, these documents actually fall into the “Proposed Rules” category and requested that FDA reclassify these notices of filing documents as proposed rules. This change is effective immediately.

I. Background

Section 409 of the FD&C Act (21 U.S.C. 348) establishes the food additive petition approval process for food additives for use in human and animal food. Section 409(b)(5) requires that the Secretary of Health and Human Services publish notice in general terms of the receipt of a petition within 30 days of its filing. Similarly, section 721 of the FD&C Act (21 U.S.C. 379e) establishes a petition approval process for color additives used in food, drugs, cosmetics, and devices, and requires that the Secretary publish notice in general terms of the receipt of a color additive petition within 30 days of its filing. These responsibilities of the Secretary