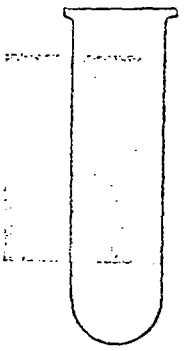
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FDA DECIDES TO END USE OF "POST-SANCTION" LETTERS

The Food and Drug Administration has decided to eliminate the use of so-called "post-sanction" letters permitting minute levels of indirect additives in food from packaging uses.

The decision to discontinue the practice came as a result of an industry dispute in which a company challenged the legality of an informal approval held by another only to find out that the "post-sanction" letter was, in fact, valid.

The use of the letters has been in dispute at FDA for some time, but the new controversy resulted in a reappraisal of the practice. The letters, which are sometimes used to inform inquirers that they have "no food additive problem," based on the minute or trace levels of migration expected, will not be revoked under the new policy.

A New Subpart under §121 to Be Used to List Minor Migrants

However, FDA-ers will now require a listing under a new §121 subpart for "insignificant" levels of migrants from food packaging materials. Data required for this type of listing are not expected to be as extensive as now expected from firms who go through the Food Additive Petition process to clear indirect additives with problems of toxicity.

FDA-ers are now attempting to establish guidelines for this type of procedure.

Current feeling at FDA is that substances fall into only three categories: (1) Prior sanctions; (2) "Generally recognized as safe;" and (3) Regulated additives.

The new listings will bring these indirect additives into regulated status, and, once published, unless protected by patents, like other Food Additives, can be manufactured by any company.

The current dispute erupted from a competitive battle. One firm held a letter; the other did not. FDA decided the "post-sanction" letter to one resulted in a competitive advantage.

The new approach is expected to put all companies on an equal footing.