Dec. 1, Page 6), Schmidt noted "part of the memorandum of understanding concerned the approval of ingredients used in alcoholic beverages. It is our desire to develop a new memorandum of understanding that would cover this activity, and I look forward to our continued cooperation."

The Commissioner formally ended the current agreement between BATF and FDA, which had been published only last fall (See FOOD CHEMICAL NEWS, Oct. 7, 1974, Page 2; and Oct. 14, 1974, Page 20) because BATF had decided not to require ingredient labeling on alcoholic beverages.

He explained that "that action was inconsistent with our memorandum of understanding because the Federal Food, Drug, and Cosmetic Act requires ingredient labeling of all foods, including alcoholic beverages, unless expressly exempted from the requirement."

"Therefore, in accordance with the provision...permitting either party to terminate the agreement upon a 30-day advance written notice to the other," the Commissioner continued, "I am hereby terminating the agreement effective Dec. 19, 1975."

●

PCB COURT DECISION SUPPORTS "FOOD ADDITIVE" STATUS FOR INCIDENTAL ADDITIVES

The U. S. Court of Appeals for the 1st Circuit, in upholding the Food and Drug Administration's determination that polychlorinated biphenyls present in paper food packaging are "food additives" (See FOOD CHEMICAL NEWS, Dec. 1, Page 2), relied on language in the House and Senate reports on the 1958 Food Additives Amendment to support its determination.

Natick Paperboard and Crown Paperboard had appealed a District Court decision that FDA could seize paperboard containing over 10 p.p.m. PCB as "adulterated food," arguing that food packaging material is not "food" within the meaning of the Act, and therefore is not subject to seizure as "adulterated food."

The agency had announced its intention to seize paper food packaging material containing over 10 p.p.m. PCBs and shipped in interstate commerce as "adulterated food" in 1973 when its attempt to regulate PCBs in paperboard packaging materials as food additives was delayed by a request for a hearing, which is currently in its preliminary stages (See FOOD CHEMICAL NEWS, Oct. 27, Page 2).

In declaring that FDA has the right to seize paper food packaging material as "adulterated food," if it contains over the 10 p.p.m. limit of PCBs, the Appeals Court, in the Nov. 26 decision written by Senior District Judge Thomsen, cautioned:

> "We do not hold, however, that FDA can properly take steps to seize any and all paperboard containing PCB's in excess of 10 p.p.m. wherever it is located and whatever its intended use may be."

DSW 323577

The FDA "must be able to prove that any paperboard intended to be seized before it has actually been used as a container for food" is either in the hands of a packager of food, or "in transit to, ordered by, or being produced with the intention that it be sold to a packager of food," the Court stated, or in some way meets the definition of "food additive."

Also, the decision stated, "if the packager or other claimant can show that the food placed in or to be placed in the paper container is or will be insulated from PCB migration by a barrier impermeable to such migration, so that contamination cannot reasonably be expected to occur, the paperboard would not be a food additive and would not be subject to seizure under the Act."

"So interpreted," the Appeals Court concluded, "the notice of intended seizure is not overbroad," as contended by Natick and Crown.

Turning to the language in the House and Senate reports on the Food Additives Amendments to support FDA's contention that PCB's in paper food packaging material may be termed "food additives" and that paper food packaging material containing over 10 p.p.m. PCBs may be seized as "adulterated food," the Appeals Court decision, in a footnote, observed that "Both the House and Senate Reports on the Food Additive Amendment contain the following...:

> "'The legislation covers substances which are added intentionally to food. These additives are generally referred to as intentional additives.
>
> "'The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. Those substances are generally referred to as incidental additives.
>
> "'The principal example of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.'"

The public is protected from "unsafe food additives," the Court declared, by §402(a) which provides "that a food shall be deemed adulterated if it is, or it bears or contains any food additive which is unsafe. . ."

"Unsafe food additives," the Court concluded, "whether intentional or incidental, are 'adulterated food'...and, therefore, may be seized..." The decision added:

> "It would defeat the policy of the Act to require, as plaintiffs contend, that FDA must wait until the unsafe food additive has actually entered or come in contact with food before it can be seized; it is enough that FDA has reasonable cause to expect that the additive will be used in such a way as to enter or otherwise come in contact with food. To wait until actual contamination

STLCOPCB4075226

occurs, in the warehouse of the food processor, on the shelf of a grocery store, or in a family kitchen would effectively deny FDA the means to protect the public from adulterated food..."

Supporting the agency's 10 p.p.m. limit on the PCBs, the Court noted, "The affidavits before the district court justify the conclusions that PCB's are toxic, that they tend to migrate from paper packaging material to the contained food by a vapor phase phenomenon, that paper packaging material containing PCB's in excess of 10 p.p.m. is not generally recognized as safe for packaging food for human consumption unless the food is protected from such migration by an impermeable barrier, and that if so used, without such barrier, paper food packaging containing PCB's 'may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of *** food'..."

Therefore, "paper food packaging material containing PCB's in excess of 10 p.p.m. will in many instances be an 'unsafe food additive,'" the decision stated.

FDA HOPES TO RESOLVE SOFT DRINK LABELING ISSUES "SOON"

The Food and Drug Administration is considering the several issues of soft drink labeling currently pending, and hopes to resolve them soon, FDA-ers Dr. Howard R. Roberts, Acting Director of the Bureau of Foods, and Taylor M. Quinn, Director of the Division of Regulatory Guidance, assured representatives of Coca-Cola recently.

The Coca-Cola representatives had prepared a letter outlining the many labeling problems facing the soft drink industry, and, in particular, the diet soft drink industry. In the letter, Coca-Cola urged that FDA should "devote whatever resources are reasonably appropriate to a one-time resolution of all the labeling issues..."

At the meeting, the FDA-ers assured the firm's representatives that the agency:

(1) is considering the "several petitions" on labeling of secondary packaging for soft drinks, such as returnable cartons, "and hoped to rule on them before long."

The letter noted that under the terms of a new regulation (See FOOD CHEMICAL NEWS, June 30, Page 27), "FDA will regard open type cartons as 'packages' if they bear any mandatory labeling information," creating a problem for soft drink producers, particularly in multi-flavor lines, such as Coca-Cola's 14-flavor FANTA products.

"A separate but related problem arises in those instances in which a trademark also functions as an identity statement pursuant to the Soda Water Standard (e.g. Coca-Cola and Sprite)," the firm's letter pointed out, noting that this situation was covered in a petition filed by the National Soft Drink Association (See FOOD CHEMICAL NEWS, Sept. 1, Page 21).