by the 1990 amendments; i.e., it had changed from a special dietary use claim that was directed at a limited segment of the population to a nutrient content claim directed to the general population. Thus, FDA was not merely proposing to change the location of the provisions on this claim. It was asking whether the ''sugar free'' claim is an appropriate nutrient content claim, and whether it is appropriate to retain the qualifiers that had been used to clarify this claim.

The question that the objectors' arguments raise is whether the agency's decision that the ''Useful Only in Not Promoting Tooth Decay'' statement is a health claim, under the requirements of the 1990 amendments, and that it cannot be used as a qualifier of the nutrient content claim, is the logical outgrowth of the proposal. In *Chocolate Manufacturers Association* v. *Block*, 755 F.2d 1098, 1105 (4th Cir. 1985), the Fourth Circuit said that the question that the logical outgrowth test raises is whether the final rule materially altered the issues involved in the rulemaking; that is, whether the final rule substantially departed from the terms or substance of the proposed rule.

In its final decision on the ''Useful Only in Not Promoting Tooth Decay'' statement, FDA was acting well within the scope of the proposed rule. The issue in the proposal was whether ''sugar free'' and its qualifiers constituted an appropriate nutrient content claim, and that is the issue that the agency decided in the final rule.

The key point in considering the adequacy of the notice that FDA provided is the fact that FDA never specifically raised the question of whether the ''Useful Only in Not Promoting Tooth Decay'' qualifier could be considered to be a health claim. The question that, thus, must be considered is whether this omission was sufficiently significant as to provide a basis for concluding that the agency did not give proper notice.

This question is answered by *International Harvester Co.* v. *Ruckelshaus*, 478 F.2d, 615, 632 n.51 (D.C. Cir. 1973). In Footnote 51, the court stated:

> As we have stated in an analogous context of rule-making proceedings before the Federal Communications Commission, where petitioners have argued that the Commission was ''changing the rules in the middle of the game'' when it took into consideration factors not specifically indicated in its Section 4(a) notice under the Administrative Procedure Act, 5 U.S.C. § 1001(a), ''[s]urely every time the Commission decided to take account of some additional factor it was not required to start the proceedings all over again. If such were the rule the proceedings might never be terminated.'' *Owensboro On the Air* v. *United States*, 104 U.S. App. D.C. 391, 397, 262 F.2d, 702, 708 (1958); *Logansport Broadcasting Corp.* v. *United States*, 93 U.S. App. D.C. 342, 346, 210 F.2d, 24, 28 (1954).

Thus, the agency need not have mentioned the specific factor on which it ultimately relied in the proposal as long as the basic issue remained the same, which it did.

In the nutrient content claims proposal, FDA was raising the question of whether particular statements are appropriate to be made as nutrient content claims for food products. With respect to one such statement, ''Useful Only in Not Promoting Tooth Decay,'' several comments were received in support of, and one comment in opposition to, retention of this statement as part of the ''sugar-free'' claim. FDA's decision was that this statement was not a nutrient content claim. Thus, the objectors' arguments that an adequate notice and opportunity for comment were not provided, and that the final rule was not the logical outgrowth of the proposal, are without merit.

2. In arguing that the agency had not provided adequate notice and an opportunity for comment, one objector referred to a statement by the agency concerning the persuasiveness of data in supporting the noncariogenicity of sugar alcohols (polyols) that appeared in the final rule entitled ''Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label'' (hereinafter referred to as the ''mandatory nutrition labeling final rule'') (58 FR 2079 at 2099). The firm also pointed to other statements made by FDA in reference to health claims and its intentions regarding sugar alcohols that the objector claimed evidenced that FDA's action was motivated by doubts about the validity of the ''Useful Only in Not Promoting Tooth Decay'' claim.

Nowhere did FDA say, as the objector implies, that it became aware of new data casting doubt about the noncariogenic properties of sugar alcohols. What the agency did say was that it wanted to ensure that the statement continued to be valid. It is clear, however, that the agency's final action on the ''Useful Only in Not Promoting Tooth Decay'' statement was not motivated by any concern about the continuing validity of the claim. It was based solely on the legal conclusion about the status of the claim that the agency reached after reconsidering whether to continue to provide for use of the statement in light of the comments that were submitted (see 58 FR 2302 at 2326). Thus, the objector's argument that there was no suggestion that FDA had become aware of new information casting doubt on the noncariogenic attributes of sugarless products is simply beside the point.

3. The objectors argued that the statement ''Useful Only in Not Promoting Tooth Decay'' has a long history of use, and that its history of use was as a disclaimer and not as a claim. The objectors argued that, as a disclaimer, the phrase is an integral part of the nutrient content claim ''sugar free'' and, thus, under the provisions of the last sentence of section 403(r)(1) of the act (21 U.S.C. 343(r)(1)), i.e., ''a claim subject to clause (A) is not subject to clause (B),'' cannot be treated as a health claim.

Before the passage of the 1990 amendments, how the statement ''Useful Only in Not Promoting Tooth Decay'' had been used may have had some significance in determining whether to permit its continued use. However, the agency had to review the use of the statement in view of the changed circumstances effected by the new law. Under section 403(r)(1)(B) of the act, a claim that characterizes the relationship of any nutrient which is of the type required in section 403(q)(1) or (q)(2) of the act to be in the label or labeling of a food to a disease or a health-related condition is a health claim. The statement on tooth decay meets both elements of this definition. Sugar alcohols are a category of nutrients for nutrition labeling purposes (see 21 CFR 101.9(c)(6)(iii)), and tooth decay is a disease. Thus, no matter how this claim has been used, the agency must pay attention to the law as it is now written, and the law says that if such a statement appears on the food label, it will misbrand the food unless authorized by FDA under section 403(r)(3) of the act. The agency was merely recognizing what the law requires on its face in saying in the nutrient content claims final rule that the phrase ''Useful Only in Not Promoting Tooth Decay'' is a health claim. It does not meet the definition of nutrient content claim because it does not provide any information that constitutes a nutrient content claim; i.e., that characterizes the level of any nutrient.

4. The objectors also argued that the phrase ''Useful Only in Not Promoting Tooth Decay'' is an integral, indispensable part of the nutrient content claim that provides important information to help the consumer understand the intent of the ''sugar free'' claim. In making this argument, the objectors relied on the history of the