Corrections

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This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 1987F–0179]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra

Correction

In rule document 03–19509 beginning on page 46363 in the issue of Tuesday, August 5, 2003, make the following corrections:

1. On page 46405, footnote 9 should read as follows: ''[9] CSPI also relies on its White Paper (CSPI exh. 1) and exhibits 3 through 7 to the White Paper. Although this reference is quite lengthy (approximately 230 pages total), CSPI fails to specify the information or data in these documents that support its assertion that FDA's position on carotenoids is a minority view. In such circumstances, reliance on the White Paper (CSPI exh. 1) and exhibits 3 through 7 cannot justify a hearing because a hearing will not be granted in the absence of available and specifically identified reliable evidence to support the factual issue asserted (§ 12.24(b)(2)).''.

2. On page 46408, footnote 33 should read as follows: ''[33] Elsewhere in this issue of the **Federal Register**, FDA has concluded, based upon a subsequent food additive petition submitted by P&G containing new data and information, that olestra-containing foods need not bear the information statement required by the original final rule. FDA has concluded that most of the information statement is no longer required to ensure that olestra-containing products are not misbranded. The olestra regulation, § 172.867, as revised in response to P&G's petition, requires that an asterisk appear in the ingredient list beside the added vitamins A, D, E, and K. The asterisk will reference the statement, ''Dietarily insignificant.'' The purpose of such labeling is to inform consumers that their vitamin status will not change as a result of consuming olestra-containing products. Accordingly, CSPI's objections to the olestra label statement imposed by the 1996 final rule are arguably moot.''.

3. On page 46409, in the first column, the paragraph preceding footnote 36, ''First, CSPI's first objection challenges FDA's finding that olestra is safe for use in savory snacks.[37] As noted, resolving the question of olestra's safety requires the application of the legal standard (''safe'') as defined by FDA's regulations (''reasonable certainty of no harm'') to a set of facts. As such, the question of whether olestra is safe for its intended use is a question of law, not fact. Accordingly, FDA is denying CSPI's first objection because a hearing will not be granted on issues of policy or law (§ 12.24(b)(1)).'' should be inserted in the first column, as the second full paragraph.

4. On the same page, footnote 44 should read as follows: ''[44] Olestra is not digested and thus will add to the weight of the stools of olestra consumers (61 FR 3118 at 3158). Thus, mere increase in stool weight of olestra consumers is not itself evidence of harm.''.

[FR Doc. C3–19509 Filed 10–6–03; 8:45 am]

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