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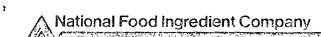
(202) 452-1300

19:40 PCA

These attachments were inadvertently omitted from our letter of June 29, 1981 to Secretary Schweiker on behalf of our client the Flavor and Extract Manufactuers' Association of the U.S. concerning the labeling of vanilla ice cream. Please see that they are attached to

Thank you.

the letter as soon as possible.



July 31, 1979

Mr. Taylor Quinn
Associate Director for Compliance
Bureau of Foods
Food and Drug Administration
Department of Health, Education, and Welfare
200 C Street, S.W.
Washington, D.C. 20204

Dear Mr. Quinn,

Your letter of May 31, 1979 to Mr. Glenn P. Witte of the International Association of Ice Cream Manufacturers has clarified the question of usage of non-vanillabean-derived natural flavors, which simulate, enhance, or resemble vanilla flavor, in vanilla ice creams, by relegating such ice cream products to Category II, assuming predominance of vanilla-bean-derived flavor. However, new questions have arisen which turn away from the ice cream standards and address themselves to the vanilla standards. We feel that similar clarification of these questions should also issue from the Food and Drug Administration.

The only flavoring agents legally acceptable in Category II vanilla ice creams'vanilla flavored ice cream'-before issuance of your above-mentioned letter
were the standardized foods vanilla-vanillin extract, vanilla-vanillin flavor,
and vanilla-vanillin powder (or sugar), as defined in 21 CFR sections 169.180,
169.181, and 169.182. These were even referred to in the trade as 'Category II
vanillas'.

Apparently, there are now circulating some very broad interpretations of your opinion letter. There is discussion of the use of vanilla with other natural flavors (WONF) in the flavoring of Category II ice cream and other food products; that is to say, with the other natural flavors physically included in the same container with the vanilla extract or flavor, so that the manufacturer of vanilla flavored ice cream may flavor his product from a single package. It is rumored that such single package vanilla WONF products are already being offered in the marketplace.

Since we are manufacturers of vanilla extracts, and of complete lines of natural flavors and artificial flavors as well, an opinion from you regarding these questions is needful to us, so that we may direct our research and development to meet the market requirements. Specifically, we need answers to the following questions:

1. May a natural but non-vanilla-derived flavoring be used in conjunction with vanilla-vanillin extract or vanilla-vanillin flavor in the flavoring of Category II, or vanilla flavored, ice cream? If so, would it be necessary to reduce the amount

of vanillin present in the vanilla-vanillin, in order to take into account the flavor contribution of the non-vanilladerived flavor...that is, to maintain the predominance of the flavor derived from vanilla beans?

- 2. If the above combination vanilla-vanillin plus a non-vanilla-derived flavoring is permissible in a Category II ice cream, may this combination be blunded together and offered in a single package? On the other hand, if the above combination is not permissible, then may the system already approved by your letter (vanilla extract or vanilla flavor plus a non-vanilla-derived flavoring) be blended together in a single package?
- 3. If either or both of the combinations is permissible, what labeling will be required. that is, what shall such products be called, and may the ingredient declaration be composed in accordance with 21 CPR 101.22(g)?

We are not experiencing difficulty with the concept of separate packaging for flavoring Category II vanilla ice cream, but are looking at the convenience to the ice cream manufacturer when we explore the questions arising over vanilla or vanilla-vanillin packaged in a single container with one or a group of other natural flavors.

Very sincerely yours, NATIONAL FOOD INGREDIENT CO.

James (C). It

Kenneth B. Basa Manager-Laboratory