September 23, 2003

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Md. 20852

Re: Draft Guidance for Industry: Channels of Trade Policy for Commodities With Which Tolerances have Been Revoked, Suspended, or Modified by the Environmental Protection Agency, Docket Number 2003D-0263, *Federal Register*, Vol. 68, No. 141, July 23, 2003

To Whom It May Concern:

The U.S. Apple Association (USApple) is the national trade association representing all segments of the apple industry. Members include 40 state and regional apple associations representing the 7,500 apple growers throughout the country, as well as more than 400 individual firms involved in the apple business. USApple appreciates this opportunity to comment on the Food and Drug Administration's (FDA) draft guidance regarding its channels of trade policy.

FDA outlines in its draft guidance a regulatory approach to deal with pesticide residue tolerances, which have been revoked, suspended or modified by the Environmental Protection Agency (EPA). This approach relies heavily on FDA's understanding of how agricultural commodities are produced, processed and distributed; how pesticides may degrade over time; and when a pesticide was last lawfully applied.

USApple is concerned that this approach may endanger apple growers, marketers and processors who rely on pesticide tolerances to guarantee the integrity of apples and apple products in the marketplace. Specifically, USApple is concerned that FDA may overestimate the degradation of pesticide residues on apples and processed commodities, underestimate the time products are in commerce and miscalculate the last lawful pesticide application date.

Pesticide tolerances are rarely removed because of imminent dietary concerns. The majority of tolerances are removed for economic or administrative reasons. In these more routine cases EPA maintains tolerances to allow growers time to use existing stocks without establishing a final use date. EPA also allows considerable time for processed products to clear channels of distribution before tolerances are revoked. USApple strongly recommends EPA continue to adhere to this policy, which would make FDA's planned approach for tolerance enforcement unnecessary. Should EPA expedite the removal of tolerances, FDA's proposed policy could wrongfully subject that food to possible regulatory action, since the last date of legal application will be unknown.

703 442-8850
800 781-4443
fax 703 790-0845
Web site www.usapple.org
8233 Old Courthouse Road, Suite 200 ★ Vienna, VA 22182-3816 USA

USApple urges FDA not to use residue decline information to establish a date when pesticide residues should be nondetectable. Available residue decline data should not be used to establish the legal presence of a pesticide residue because available data may be unreliable and unrepresentative, and therefore, inappropriate for this purpose. This type of error would be compounded by the potential to miscalculate the last lawful use date, since this date is usually unknown.

In cases where a tolerance revocation is not the result of a dietary risk concern, FDA should assume that a pesticide residue could be legally present in any processed apple product for a minimum of four years, before it requires firms to make a showing that residues were present as a result of a legal application. This allowance should be made because FDA will be unable to accurately determine the last lawful use date in most routine tolerance revocation cases, and processed products could remain in channels of distribution for four years.

USApple appreciates this opportunity to comment on this important issue.

Sincerely yours,

James R. Cranney, Jr.
Vice President

cc: USApple Board of Trustees
Jim Jones, EPA