Privacy Client Advisory

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KELLEY DRYE COLLIER SHANNON

FTC and FDA Testify on Capitol Hill on Dietary Supplements

EXECUTIVE SUMMARY

On March 9, 2006, C. Lee Peeler, Deputy Director of the Federal Trade Commission's Bureau of Consumer Protection, and Robert Brackett, Ph.D., Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition ("CFSAN"), testified on behalf of their agencies before the House Committee on Government Reform about the regulation of dietary supplements.

Peeler's testimony included information on the FTC's efforts to protect consumers from false or misleading marketing of dietary supplements, with specific emphasis on the safety of young consumers. Brackett provided information on FDA's efforts in this area including the latest on adverse event reporting ("AER") and the status of FDA's proposed regulation on dietary supplement food manufacturing practices ("GMP").

The FTC and FDA share concurrent jurisdiction over dietary supplements and other health and nutrition products – FTC over advertising and FDA over labeling. The agencies work closely together to police the marketplace for deceptive and unsubstantiated claims and for products that present safety concerns. They also work with other local, state, and federal government entities such as the Office of Dietary Supplements of the National Institutes of Health ("NIH").

FTC DIETARY SUPPLEMENT ADVERTISING PROGRAM

FTC Dietary Supplement Advertising Program Peeler testified that the FTC has focused its enforcement on national advertising claims for:

1. products with unproven benefits;
2. products promoted to treat or cure serious diseases;
3. products that may present significant safety concerns to consumers; and
4. products that are deceptively marketed to or for children and adolescents.

FTC ENFORCEMENT AND EFFORTS TO PROTECT YOUNG CHILDREN

In the past year, the FTC has filed 14 complaints, obtained orders against 40 companies and 44 individuals making allegedly unsubstantiated or false advertising claims for dietary supplements and other healthcare products, including oral sprays, creams, and patches. These orders have required the defendants to pay a total of $35.7 million in consumer redress, disgorgement, and civil penalties.

Peeler testified that "[t]he agency's efforts to police the supplement marketplace include especially close scrutiny of products marketed for use by children or otherwise targeted to appeal to young consumers."

The FTC has taken action against allegedly deceptive advertising for children's supplements marketed as various health

aids, including:

1. cold prevention products;
2. treatment for attention deficit/hyperactivity disorder (AD/HD);
3. natural alternatives to steroids for young bodybuilders; and
4. weight loss products.

FDA ENFORCEMENT

Brackett testified that from October 2002, through February 2006, FDA has conducted 588 domestic inspections of dietary supplement manufacturers, issued more than 350 warning letters and cyber letters to marketers of dietary supplements, seized products worth over $13.4 million, and supervised the voluntary destruction of more than $3.0 million worth of illegally marketed dietary supplements. Bracket also noted that FDA has obtained permanent injunctions against 5 firms distributing misbranded or unapproved drugs as dietary supplements, and has stopped more than 4,000 foreign shipments of potentially unsafe or misbranded dietary supplements from entering the United States

ADVERSE EVENT REPORTING

CFSAN's AER system is a computerized system for voluntarily reports by industry, health care providers, and consumers. Brackett testified that efforts are ongoing to incorporate a thesaurus of botanically-derived ingredients used in dietary supplements into the AER database to enable more sophisticated searching, and to create a thesaurus for cosmetic ingredients. He noted that FDA is planning a web-accessible, second generation AER system, and that the agency sought funds for the project in its 2007 budget request.

Brackett also outlined "ideal" aspects of any AER legislation:

1. the speed with which FDA would receive adverse events;
2. the ability to work with other government bodies, such as the FTC; and
3. the required inclusion of more specifi city about ingredients in an AER.

DIETARY SUPPLEMENT GOOD MANUFACTURING PRACTICES

Brackett commented on the status of FDA's proposed dietary supplement GMP regulation, stating that "[t]his regulation is under review at the Office of Management and Budget." He gave no additional information on the effective date of the pending regulation. Currently, dietary supplement manufacturers are subject to the same GMP requirements as foods.

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FOOD AND DRUG LAW PRACTICE GROUP

Kelley Drye Collier Shannon's team of Food and Drug lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising,

our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

FOR MORE INFORMATION

Kelley Drye Collier Shannon is on the forefront of food and drug industry guidelines and regulations.

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