FOOD AND DRUG ADMINISTRATION
ENFORCEMENT STRATEGY
July 15, 2010

The Food and Drug Administration (FDA) is articulating its enforcement strategy in order to ensure strategic alignment within the Agency and express why enforcement is critical to protecting public health. FDA is a science-based regulatory agency with responsibility and authority to safeguard the public health and ensure compliance with the laws and regulations it administers pertaining to foods, drugs, medical devices, biologics, and tobacco products. The scope of FDA's regulatory authority is determined by the Federal Food, Drug, and Cosmetic Act and other statutes. To more effectively implement these provisions, FDA often promulgates regulations which carry the full force and effect of law. The laws and regulations spell out criteria regulated entities must meet to ensure their products are safe, honestly labeled and, in the case of drugs and devices, effective. For tobacco products, FDA regulates these products based on a public health and population health standard.

Enforcing the laws and regulations is one of the Agency's highest priorities. Without effective FDA regulatory oversight and enforcement, some regulated entities will disregard even the clearest regulations or will not be adequately vigilant to ensure compliance with the law, potentially harming the public. Effective enforcement also ensures: that businesses remain vigilant about their corporate responsibility to comply with the laws enforced by FDA; that firms invest in quality systems that prevent harm to the public; and that those who do comply with the law are not unfairly disadvantaged.

FDA monitors and maintains industry compliance in a variety of ways, such as conducting inspections of regulated entities; collecting and analyzing domestic and import samples; reviewing FDA-regulated import entries; and taking and publicizing enforcement actions when violations are found. Not only can inspections and analyses serve as a deterrent against noncompliance, they provide a valuable source of information to FDA and important feedback to the inspected entity. If, during an inspection, investigation and/or through a laboratory analysis, a significant violation is identified, FDA will determine as quickly as possible what further agency action might be necessary. FDA will use any and all available enforcement tools, as appropriate, based on the facts of the case and the nature and seriousness of the violation. After initiating an advisory, administrative or judicial action, FDA will follow-up promptly to assess whether the regulated entity has made required changes in its practices.

Of utmost importance is ensuring that foods, biologics, drugs, and medical devices available to the consumers are safe. When FDA obtains information that an FDA-regulated product poses a significant risk to the public health, our first priority will be to determine whether the product should be removed from the marketplace and if so, to take swift action to ensure such removal and notification. This can be accomplished either by voluntary effort on the part of the responsible firm or, when voluntary action is not rapid or complete or the company is not responsive, through use of FDA's enforcement tools.

FDA will continually evaluate its enforcement processes to make sure that they are effective and efficient, and make improvements as needed. FDA will use risk informed approaches to compliance and enforcement activities focusing both Agency and industry attention on critical

areas. All FDA components are committed to swift, aggressive enforcement actions to protect the public health.

FDA will clearly communicate its enforcement strategy and priorities and implement them in a vigilant, strategic, swift and visible manner. The agency will document its enforcement policies in the Manual of Compliance Policy Guides and the FDA Regulatory Procedures Manual, both of which are available to the public on-line at www.fda.gov. Additionally, FDA will disclose promptly to the public as much information as possible about its enforcement activities. FDA recognizes that such disclosure fosters compliance and serves to educate consumers about risks.

At a time when FDA regulated entities are a part of a complex and globalized supply chain, it is imperative that FDA develop strong relationships with its regulatory partners. In the domestic arena, FDA will collaborate with and enlist the cooperation of our federal, state, and local public health protection and law enforcement counterparts to develop and implement effective risk control and enforcement strategies. In the import arena, FDA will take action to prevent unsafe or ineffective products from entering U.S. commerce and will work closely with the Customs and Border Protection, Department of Homeland Security, to pursue appropriate remedies and punishments for violations. In the international arena, FDA will work to foster and strengthen working relationships with its international regulatory and law enforcement counterparts, to establish effective partnerships, to share information, and to develop and implement effective risk control and enforcement strategies. FDA will also reach out to its international partners to take rapid action, as appropriate under their authorities, while it alerts the public and prepares longer-term responses.

Businesses and persons who make FDA-regulated products have a legal and ethical duty to protect the health and safety of consumers by adopting and faithfully implementing rigorous quality management systems that ensure continuous compliance with the food and drug laws. Violations of FDA laws and regulations, whether intentional or unintentional, are unacceptable and may be addressed civilly and with criminal sanctions.

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