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Current Issues Affecting FDA-Regulated Companies

FDA Law Update

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EU Cosmetics Regulation Receives Welcome Facelift

Last month, the European Parliament approved new rules that will increase cosmetic safety and simplify regulatory procedures in the European Union. The legislation, which resulted from a compromise negotiation between Parliament and Council representatives, will take the form of a single regulation that applies to all member states simultaneously, and will replace the patchwork of 27 sets of national rules and 55 amendments that comprise the EU Cosmetic Directive of 1976.

The new text will increase manufacturer responsibility and strengthen market surveillance, while establishing clear guidelines that will cut administrative costs and unnecessary litigation. Noteworthy changes include:

Notification, Assessment, and Labeling of Nanomaterials. For the first time, Parliament introduced laws regulating cosmetics containing nanomaterials, which the new text defines as "an insoluble or bio-resistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm." Nanomaterials, which may be thousands of times finer than a human hair, and estimated to be in about 5% of cosmetic products, are now subject to compulsory notification, safety assessment, and labeling measures. For instance, a manufacturer must inform the European Commission (the "*Commission*") six months prior to launching a product containing nanomaterials. If there is a safety concern, the Commission will consult the Scientific Committee on Consumer Safety for an opinion. Additionally, all nanomaterials in the cosmetic must be mentioned on the list of ingredients on the packaging, with the names of such ingredients followed by the word "nano" in brackets.

Strict Treatment of CMR Substances. The regulation essentially forbids the use of substances in cosmetics that are carcinogenic, mutagenic, or toxic for reproduction ("*CMR*"), which may only be used in exceptional cases under strict conditions. A new clause also addresses substances with endocrine-disrupting properties, which will be regulated when European or internationally agreed upon criteria for identifying such substances are available, or five years after the regulation is in force. However, the rules still allow for the continued use of ethanol, which is widely used in perfumes.

Common Criteria for Product Claims. The regulation provides that labeling and advertising of

cosmetics may only mention the real effect of a product. The Commission is asked to draw up an action plan and adopt a list of common criteria for claims which may be used in connection with cosmetics.

Strengthening In-Market Control. The regulation creates a single, central notification system overseeing cosmetics that will replace various national procedures. Additionally, new provisions increase market surveillance cooperation between authorities, reinforces a tracing system that ensures identification of a product through the supply chain, monitors undesirable side effects induced by a product, and sets up minimum requirements for the manufacturer in assessing product safety.

Once approved by the Council, the regulation will enter into force 20 days after publication in the EU Official Journal, and will apply 42 months later (2012), except for certain parts on nanomaterials and CMR substances that will apply from an earlier stage. Existing provisions concerning animal testing on cosmetics from now until 2013 will remain intact.

Generally, the new amendments have been favorably received. With these changes, Parliament has expressed its aim to "remove legal uncertainties and inconsistencies, while increasing the safety of cosmetics." Additionally, these improvements may influence other countries such as the U.S., whose cosmetics regulations are less clear and less stringent, to take notice and toughen up.