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May 20, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration, rm 1061
5630 Fishers Lane
Rockville, MD 20852

Subject: Docket No. 02N-0204
Bar Code Label Requirement For Human Drug Products and Blood;
Proposed Rule

Dear Sir or Madam:

Following are comments on the Agency's proposed rule for the "Bar Code Label Requirement For Human Drug Products and Blood".

Colgate-Palmolive Company supports the Agency's efforts to Bar Code certain drug product labels in an effort to reduce medication errors. However, Colgate-Palmolive Company questions the applicability of bar coding to prescription dental drugs.

The Agency included all prescription drugs in the proposed rulemaking because the Agency was "unaware of any prescription drug products that are not used in hospitals". Colgate-Palmolive Company respectfully points out that a number of prescription dental drugs are not used in hospitals or other institutional settings. These prescription dental drugs include but are not limited to in-office fluoride treatments for children, office irrigation products, and prescription level fluorides for use at home as supplements for children (in areas where the water is not fluoridated) or for adults with rampant caries. These products are applied by dentists in-office or prescribed by the dentist or pediatrician for home use. The products are not used in an institutional health care setting. Therefore bar coding of such dental drugs serves no purpose for the consumer, as the drugs are not being used in a setting where they can be scanned. In fact, requiring bar coding of such drugs would be detrimental, as it will increase the cost of such drugs, an increase that would most likely ultimately be passed onto the consumer.

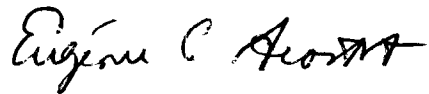
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In conclusion, Colgate-Palmolive Company is requesting that the scope of the final rulemaking be limited to those prescription drugs used in hospital or other institutional setting with scanning capability.

Please feel free to contact me at (732)-878-7468 should you have any questions concerning these comments.

Sincerely,

A handwritten signature in black ink, reading "Eugénie C. Acosta". The signature is written in a cursive style with a prominent initial "E" and a stylized "A" at the end.

Ms. Eugénie C. Acosta
Manager, Regulatory Affairs