COLGATE-PALMOLIVE COMPANY

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

Subject: Docket No. 00N-1484
Safety Reporting Requirements for Human Drug and Biological Products;
Proposed Rule

Dear Sir or Madam:

Following are comments on the Agency's proposed rule for the "Safety Reporting Requirements for Human Drug and Biological Products".

Colgate-Palmolive Company supports the Agency's efforts to amend their pre-and postmarketing safety reporting requirements for human drug and biological products to harmonize them with international reporting requirements. However, Colgate-Palmolive Company has some comments on the applicability of some of the proposed regulations to dental products.

1. FDA has specifically stated that a licensed physician be responsible for the content of postmarketing safety reports, and 3500A's. Colgate-Palmolive Company respectfully points out that depending on the actual products involved there are other qualified scientific experts that would be as effective as a licensed physician (ex. Dentists for Dental products, Optometrists for Optical products, etc.). These qualified experts receive specialized training in handling adverse drug reactions, and have knowledge of effects on particular body systems. Therefore Colgate requests that FDA replace licensed physicians with qualified scientific experts for the responsibility of the content of postmarketing Safety reports and 3500A's.

2. The proposed rule would require 'active query' (direct verbal contact in person or by telephone) be used to acquire information from the initial reporter. Though Colgate agrees that this is an expeditious way to acquire safety information it is not always possible on a global basis. For instance, there is a 14 hour time difference between

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Australia (where some of our IND clinical studies are performed) and the United states where our healthcare professionals responsible for US pharmacovigilance are located. Hence, the IND investigator (initial reporter) and the healthcare professional with responsibility for FDA safety reporting would not have any overlapping business hours during which to make telephone calls. In this situation Email would be the most expeditious means of communication. Therefore, Colgate-Palmolive Company requests that the definition of active query be expanded to include Email communication.

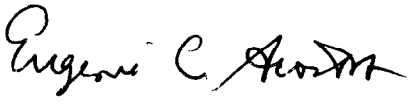
3. It is important to point out that all products that are regulated by FDA as drugs are not necessarily marketed as a drugs outside of the US. Products, such as Colgate's NDA toothpaste, Colgate Total, are regulated as cosmetics in some regions outside of the US. Similar to the US, cosmetics in other global regions are not subject to any mandatory safety data collection/reporting requirements. In such cases, the worldwide marketing status and worldwide patient exposure data requested by FDA in the Periodic Safety Update Report (data related to marketing authorizations, SADR's, lack of efficacy reports, safety assessments) would be nonexistent. Hence, Colgate requests that the amount of information required to be collected for such products be reduced (by deletion of the worldwide reporting requirements) in comparison to products that share pharmaceutical status on a global basis.

In conclusion, Colgate-Palmolive Company requests:

- that qualified scientific experts replace license physicians for the responsibility of the content of postmarketing safety reports, and 3500A's,
- that the definition of "active query" be expanded to include Email communication,
- and a reduction in the scope of the required safety data for products regulated as drugs in the US but as cosmetics in other regions of the world.

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

Sincerely,



Ms. Eugénie C. Acosta
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