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February 4, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5360 Fishers Lane, rm.1061  
Rockville, MD 20852

**Subject: Colgate-Palmolive Response to the Agency request for comments on Docket No. 2003N-0529: Amending the MedWatch Forms to Collect Postmarketing Adverse Event Data Relating to Race and Ethnicity.**

Dear Sir/Madam,

The Colgate-Palmolive Company submits the following comments to the above docket which requests comments on Amending the MedWatch Forms to Collect Postmarketing Adverse Event Data Relating to Race and Ethnicity.

The Colgate-Palmolive Company does not believe that the proposed rulemaking fully takes into account global considerations. According to 21 CFR 314.80 the Agency requires reporting of adverse events from foreign as well as domestic sources.

In the European Union Article 8.1 and Article 25 of EU Directive 95/46/EC entitled "Directive on the Protection of individuals with regard to the processing of personal data and on the free movement of such data", which is currently in effect will cause significant difficulties regarding the collection and transfer of race and ethnicity data for companies operating in Europe.

Article 8.1 is concerned with the collection of such data and states "All member states shall prohibit the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, and the processing of data concerning health or sex life." Article 25 is concerned with the transfer of personal data between countries and requires an adequate level of data protection to allow any personal data to be transferred.

Since the strategies for implementing the above articles varies among the EU member states and the member state laws also differ the systematic collection

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and transfer of race and ethnicity information will cause compliance issues if required by the Agency.

The Colgate-Palmolive Company therefore believes that amending the MedWatch form to include the systematic collection of ethnicity and race information would lead to an increase in data privacy issues and compliance as it relates to how information is collected, maintained and shared between countries for adverse events originating in the European Union and other areas with similar privacy laws including Canada and Australia. This would also become an issue in the many other countries which are considering similar data privacy requirements.

In addition the solicitation of ethnicity and race information has the potential to alienate the consumer or reporter when this type of sensitive personal information is requested during a stressful situation leading to possible difficulties in gathering pertinent facts regarding any alleged adverse event.

Please feel free to contact me should you have any questions regarding this comment.

Respectfully,



Eugénie C. Acosta, RAC  
Manager, Regulatory Affairs