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VIA ELECTRONIC FILING

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

**RE: Docket Nos. 1992N-0297(formerly 92N-0297), 1988N-0258 (formerly 88N-0258), 2006D-0226,
Prescription Drug Marketing Act Pedigree Requirements;
Effective Date and Compliance Policy Guide; Request for Comment**

Dear Sir or Madam:

Talecris Biotherapeutics (Talecris) welcomes the Pedigree Requirements of the Prescription Drug Marketing Act becoming effective on December 1, 2006. It is anticipated that this federal requirement will enable the different states to harmonize their requirements. Talecris also appreciates the opportunity to provide comments on the Draft Compliance Policy Guide 160.900, entitled "Prescription Drug Marketing Act Pedigree Requirements Under 21 CFR Part 203." Talecris is a manufacturer of premium protein therapies providing products into the United States marketplace.

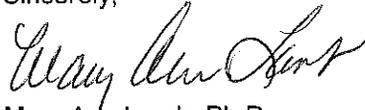
Talecris wishes to contribute to the discussion on the following points.

1. The Federal Register Notice (*Federal Register*, 71 (114) p. 34249-34251) asks for comment on providing a list of drug products that have been counterfeited in the past in the Compliance Policy Guide (CPG). While providing a list of drug products that have been counterfeited in the past has merit, providing a list of products that are susceptible to being counterfeited or diverted would be more appropriate. Talecris suggests that this list should be based on the previously available National Association of Boards of Pharmacy (NABP) list (National Specified List of Susceptible Products) of the top 32 drugs susceptible to counterfeiting or diversion. The State of Florida has based their Specified Drug List for Pedigree Papers on that list (<http://www.doh.state.fl.us/pharmacy/pedigree%5Fpaper%5Frequirements.htm>).
2. In the CPG under FACTOR 1: High Value In the US Market, question 2 (*Is the drug product a "high priced/specialty" product used for a serious or life threatening disease?*), the Talecris immune globulin intravenous (IGIV) product Gamimune is mentioned. Talecris suggests that in addition to Gamimune, the Talecris IGIV product Gamunex also be mentioned on this list of examples.
3. In the CPG under FACTOR 1: High Value in the US Market, question 4 (*Is there a shortage of the drug?*), a web address is provided for access to the list of drugs regulated by CDER that are currently in short supply. A list of biologics regulated by CBER that are currently in short supply is also available. Talecris suggests that the web address for this list (<http://www.fda.gov/cber/shortage/shortage.htm>) also be included.

4. Talecris understands that due to resource constraints, the enforcement efforts by the FDA will need to be prioritized. Talecris advocates that the FDA assign a high priority to the secondary market (gray market) for IGIV products. This gray market, which negatively impacts cost of therapy and availability of affordable product, may be discouraged by implementation and enforcement of a pedigree program for IGIV products.

Thank you for the opportunity to provide comments.

Sincerely,



Mary Ann Lamb, Ph.D.
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