

**San Diego
Blood Bank**
A Regional Blood Center



September 24, 1999

Dockets Management Branch (HFA09305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. 99D092013: Cooperative Manufacturing Arrangements for
Licensed Biologics**

To Whom It May Concern:

This letter is to comment on the Food and Drug Administration's (FDA) notice regarding the draft guidance entitled "Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics", announced in the Federal Register of August 3, 1999.

Section V. Shared Manufacturing Arrangements

This section outlines the definition of each license applicant in shared manufacturing and states that neither party holds a license for all aspects of manufacturing. The definition does not allow for either party to be fully licensed.

Many blood collection organizations have entered into agreements with other blood collection organizations to share the manufacturing of blood and blood components. The most common arrangement is where one facility collects, processes, labels and distributes all components and the other blood collection facility tests those same blood components. Both organizations are fully licensed to manufacture the blood products, but economically, it is more feasible for one facility to perform all the testing. The responsibilities seem to most closely fit description of "shared manufacturing", however, the definition offered in the draft guidance indicates that both manufacturers are only licensed for part of the process, not all. As indicated before, in the blood industry, both manufacturers are usually fully licensed. We respectfully request that the definition of shared manufacturing be updated to include two fully licensed manufacturers.

99D-2013

C3

Thank-you for this opportunity to comment on FDA's draft "Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics". If you have any questions, please feel free to contact me or the Director of Quality Assurance/Compliance, Ms Patricia E. Bakke, by phone at 296-6393, or by e-mail at tmelaragno@bloodbank.org or pbakke@bloodbank.org.

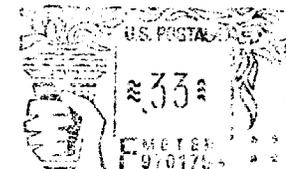
Sincerely,

A handwritten signature in black ink, appearing to read "Anthony J. Melaragno". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anthony J. Melaragno, M.D.
Medical Director/CEO
San Diego Blood Bank

**San Diego
Blood Bank**
A Regional Blood Center

440 Upas Street
San Diego, California 92103-4900



Dockets Management Branch (HFA09305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20857-0001

