496-7056

TERMS OF PROPOSAL FOR DETERMINATION UNDER SEC. 8.2(b) OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE REGULATIONS

A proposal for consideration of an 8.2(b) determination must lay a factual basis for such consideration and must show clearly that assignment to the grantee institution will result in the invention being more adequately and quickly developed for widest use, and that there are satisfactory safeguards against unreasonable royalties and repressive practices.

In making a proposal, the following points must be included:

1. The Granting of an exclusive license to a competent manufacturer for a limited period in order to develop the invention for commercial use is a necessary incentive to call forth private risk capital and expense to bring the invention to the point of practical application, and that such a period of exclusivity would not deter or restrict the use of the invention for the health and benefit of the public.

2. If available, evidence of interest of a qualified manufacturer or manufacturers in developing the invention for the market and the terms of any proposed contract with the manufacturer.

3. An estimate of the cost of producing the invention for the market.

4. Provisions for (a) all sales to the Government to be royalty-free, (b) royalty rates to consumers, other than government agencies, not to be in excess of normal trade practice under competitive conditions on similar products, (c) dedication of the invention to the public by making licenses generally available on a royalty-free and nonexclusive basis after the period of exclusivity has expired, and *(d) clinical data relating to the use of the compound to be promptly published after the period of exclusivity has expired.

5. Reservation of a nonexclusive, irrevocable, royalty-free license in the invention to the Government (including any agency thereof, State, or domestic or municipal government), with power to practice and have practiced (make or have made, use or have used, sell or have sold) throughout the world by or on behalf of the Government of the United States.

*Include only if applicable.

6. Provision for written reports, at reasonable intervals, when requested by the Government, on the commercial use that is being made, or is intended to be made, of the invention.

7. Provision for the Government to require the granting of a license to an applicant on a nonexclusive, royalty-free basis if the grantee institution has not taken effective steps within three years after a patent issues on the invention, to bring the invention to the point of practical application, or has not made the invention available for royalty-free licensing, or on terms that are reasonable, in the circumstances, or cannot show why the grantee institution should retain the principle or exclusive rights for a further period of time, and

8. Provision for the Government to have the right to require the granting of a license to an applicant royalty-free on terms that are reasonable in the circumstances to the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill health needs, or for other public purposes stipulated in the grant.

hearing?

Revised November 1966