

Draft Memo, 1/3/77, TGF

To: Russell M. Roberts  
From: Patent Council

We wish to  
join in the  
recommendations  
made by Stuart  
Whaley's  
memo 1/14/76

Subject: Notice of Intent to Amend the Department's Freedom of Information Regulation.

This refers to your memo dated November 29, 1976, requesting comments and suggestions on how best to amend the R3g Department's Freedom of Information Regulation. This office is concerned only with the 2nd paragraph of the subject notice and ~~comments~~ submits the following comments. ~~of intent are set forth below:~~

~~XXXXXXXXXXXX~~ This office is concerned with intellectual property which includes, among other things, inventions and trade secrets. Since the adoption of the U.S. Constitution the owner of intellectual property has had the option of protecting his property rights by secrecy or by resorting to the patent system. HEW policy and the Department's Patent Regulations are based upon the patent system, ~~anything~~ <sup>but permits a period of before anything</sup> which ~~frustrates~~ <sup>frustrates</sup> the patent system frustrates HEW policy regarding intellectual property and is ~~detrimental~~ <sup>detrimental</sup> to the public interest. ~~we~~ <sup>we</sup> feel that ~~it~~ <sup>it</sup> is imperative that

intellectual property should not be released in response to a request under the Freedom of Information Act without careful ~~an~~ <sup>an</sup> evaluation by HEW employees who are competent to make such evaluation. ~~The FDA Freedom Information Regulations do not meet this test~~ Intellectual property, whether generated by a non-profit grantee ~~or by~~

a for profit contractor, may have commercial value. In many cases the value of the property cannot be determined at the time the request for release is made and may not ~~be~~ <sup>be</sup> determined until some future date when test data necessary to support a patent application becomes available through ongoing research.

Premature release of such property can effectively destroy both present and future property rights.

Without regard to the submitter's views.  
Since release on NWR release is based on a present judgment of information of which are proprietary.  
We must recognize that the FDA is required to regulate the process of regulation and not to solicit such information as it is developed by the submitter.

make these comments as early as possible but these recommendations.

Such information as it is developed by the submitter should not be released in the same manner as any information developed by the submitter.

The Department Patent Regulations provide for the waiver of greater rights to inventions made in performance of sponsored research. Grant and contract proposals, reports, etc. may contain a disclosure of potentially patentable inventions which may be proprietary to the grantee or contractor or to which the grantee or contractor may acquire greater rights. ~~These inventions may have~~ ~~ultimately~~ ~~become~~ ~~commercially~~ ~~valuable.~~ ~~The~~ ~~premature~~ ~~release~~ ~~of~~ ~~such~~ ~~materials~~ ~~over~~ ~~the~~ ~~objections~~ ~~of~~ ~~the~~ ~~contractor~~ ~~or~~ ~~grantee~~ ~~without~~ ~~adequate~~ ~~evaluation~~ ~~by~~ ~~this~~ ~~Department~~ ~~and~~ ~~without~~ ~~a~~ ~~procedure~~ ~~whereby~~ ~~the~~ ~~contractor~~ ~~or~~ ~~grantee~~ ~~can~~ ~~appeal~~ ~~a~~ ~~decision~~ ~~to~~ ~~release~~ ~~the~~ ~~materials~~ ~~requested~~ ~~under~~ ~~FOIA~~ ~~in~~ ~~spite~~ ~~of~~ ~~their~~ ~~objections,~~ ~~in~~ ~~our~~ ~~opinion,~~ ~~may~~ ~~constitute~~ ~~a~~ ~~taking~~ ~~or~~ ~~destruction~~ ~~of~~ ~~property~~ ~~without~~ ~~due~~ ~~process~~ ~~of~~ ~~law~~ ~~in~~ ~~violation~~ ~~of~~ ~~the~~ ~~5th~~ ~~Amendment~~ ~~to~~ ~~the~~ ~~U.S.~~ ~~Constitution.~~ ~~Accordingly,~~ ~~we~~ ~~feel~~ ~~that~~ ~~it~~ ~~is~~ ~~imperative~~ ~~that~~ ~~the~~ ~~Department's~~ ~~Freedom~~ ~~of~~ ~~Information~~ ~~Regulation~~ ~~provide~~ ~~for~~ ~~review~~ ~~and~~ ~~evaluation~~ ~~by~~ ~~this~~ ~~office~~ ~~of~~ ~~materials~~ ~~requested~~ ~~under~~ ~~FOIA~~ ~~when~~ ~~the~~ ~~contractor~~ ~~or~~ ~~grantee~~ ~~who~~ ~~submitted~~ ~~the~~ ~~materials~~ ~~requested~~ ~~objects~~ ~~to~~ ~~their~~ ~~release~~ ~~on~~ ~~the~~ ~~ground~~ ~~that~~ ~~the~~ ~~materials~~ ~~contain~~ ~~potentially~~ ~~patentable~~ ~~subject~~ ~~matter~~ ~~or~~ ~~trade~~ ~~secrets~~ ~~and~~ ~~a~~ ~~procedure~~ ~~whereby~~ ~~the~~ ~~contractor~~ ~~or~~ ~~grantee~~ ~~may~~ ~~appeal~~ ~~a~~ ~~decision~~ ~~by~~ ~~this~~ ~~office~~ ~~to~~ ~~release~~ ~~the~~ ~~materials~~ ~~requested~~ ~~in~~ ~~spite~~ ~~of~~ ~~the~~ ~~objections~~ ~~of~~ ~~the~~ ~~contractor~~ ~~or~~ ~~grantee.~~

*OR WITHOUT THE INPUT OF THE*

*OR* *complying with regulations*

*OR party complying with regulations*

*They*