FDA Freedom of Information Act Appeal

From: Satish Gupta (satish@doctorgupta.com)

To: fdafoia@fda.hhs.gov

Date: Thursday, October 15, 2020, 06:59 PM PDT

Dear Appeal Officer:

Reference: Request Number 2020-6326

The FDA denied the entire request. The reason given was Exemption (b)(4) of the FOIA, “Trade secret and confidential commercial information.” The FDA is required to give a reason with specificity. Is it trade secret OR confidential commercial information OR both?

A "trade secret" is defined as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." See Pub. Citizen Health Research Group. v. FDA, 704 F.2d 1280, 1284 n.7, 1288 (D.C. Cir. 1983)

“Confidential Commercial Information” has been defined by the Court as, “where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4." See Food Marketing Institute v. Argus Leader Media, 139 S. Ct. at 2366

Records Requested

The request was very specific. Only two records were requested. One is form 1571 submitted by Moderna for approval of their phase three trial of Covid-19 vaccine and the other is an attachment to this form under section number 14(9): “previous human experience”.

Form 1571

It is a three page form. The blank form is available at the FDA website. The form asks basic questions like the company’s name, officers’ names, addresses and list of attachments. None of this will fall into Trade Secret or Confidential Commercial Information. The names of the people at Moderna, who are working on the vaccine, are given in the New England Journal of Medicine article listed below.

If the FDA believes that some of this information is confidential then the FDA has a duty to redact those parts and release the rest of the form.

Attachment under Section number 14(9)

These papers would describe the previous experiences with human beings related to this vaccine trial. The company, Moderna, has to treat this information as if it is private and not shared with the public. Then only this information will be “Confidential commercial information.” See the explanation by the Court as above in the case of Argus Leader.

Moderna has already published “previous human experiences” when Moderna published the results of the phase two trials. The results were published in New England Journal of Medicine. It is available to everyone free of charge at https://www.nejm.org/doi/pdf/10.1056/NEJMoa2022483.

Since the owner of the information does not treat it as private, the FDA has no basis to call it private and confidential information. If the FDA believes it is private and confidential then the FDA has to redact those parts and give an explanation as to why it is confidential commercial information.

Please expedite this request. Covid-19 pandemic is raging and all information about it should be made available to the public as soon as possible.

Thanks

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