



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Office of Policy, Planning, and
Legislation HF-11
5600 Fishers Lane
Rockville, MD 20857

October 4, 2000

Daniel Kearns
9033 Centerway Road
Gaithersburg, MD 20879

Re: Docket Number 98A-0912

Dear Mr. Kearns:

This responds to your request for an advisory opinion "with respect to FDA's policies with regard to the significance and meaning of a FDA employee's signature on documentation generated by the employee for the agency." Your request described a situation where you stated that you were "instructed" to sign a letter requesting information from a manufacturer when you did not consider the request to be justified.

Your request for an advisory opinion sought:

- * a written statement on what official FDA policy is with regard to the meaning of a FDA employee's signature on official agency documents. You cited an excerpt from a FDA rule on electronic signatures to claim that it described "a signature's meaning."
- * a written description of "what my signature on documents produced during the course of my duties at FDA means" and ask whether your signature denotes "concurrence." You then ask that, "[i]f FDA does not believe that the signature of an FDA employee denotes concurrence, I am requesting that FDA provide a written statement of what the signature does mean. If signatures vary by grade, position, or job classification, I am requesting a listing of signature classifications and their meanings."
- * a written statement "as to whether the agency believes that controls and definitions necessary for defining signatures in the private sector should also be applied to FDA."

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APA 1

The agency is denying your request for an advisory opinion.

The Basis for the Denial

The Request Does Not Qualify for Treatment as an Advisory Opinion

Under § 10.1(a), the provisions in part 10 apply to “petitions, hearings, and other administrative proceedings and activities conducted by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and other laws that the Commissioner of Food and Drugs administers under § 5.10.”

Here, the issue concerning a signature’s meaning is not within the range of subjects covered in § 10.1(a). While an employee’s signature is, at best, an “activity” conducted by FDA, it is not necessarily an activity conducted by FDA under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or other laws administered by the Commissioner of Food and Drugs. Thus, because your request falls outside § 10.1(a), the provisions regarding advisory opinions at § 10.85 are inapplicable.

The Request, Even if it Were Treated as an Advisory Opinion, Would be Denied

Yet, even if the agency were to consider your request for an advisory opinion, the agency would deny your request. FDA regulations, at 21 CFR § 10.85(a)(2), state that a request for an advisory opinion may be denied if:

- * the request contains incomplete information on which to base an informed advisory opinion (§ 10.85(a)(2)(i));
- * the Commissioner concludes that an advisory opinion cannot reasonably be given on the matter involved (§ 10.85(a)(2)(ii));
- * the matter is adequately covered by a prior advisory opinion or a regulation (§ 10.85(a)(2)(iii));
- * the request covers a particular product or ingredient or label and does not raise a policy issue of broad applicability (§ 10.85(a)(2)(iv)); or
- * the Commissioner otherwise concludes that an advisory opinion would not be in the public interest (§ 10.85(a)(2)(v)).

Even if the agency were to consider your request under § 10.85, the agency would deny your request pursuant to §§ 10.85(a)(2)(ii), (a)(2)(iii), and (a)(2)(v).

Application of § 10.85(a)(2)(ii)

One reason for denying your request for an advisory opinion (if the agency were to consider your request as being within § 10.85) is that the request is extremely broad so that FDA cannot reasonably respond. For example, one request seeks a written statement on the meaning of an employee's signature on "official agency documents" yet that would cover a wide array of internal and external FDA communications such as internal agency memoranda, letters to consumers, warning letters, legal briefs and pleadings, as well as administrative or personnel records. These communications vary in their significance. Some communications, such as certain reports to Congress and submissions to other federal agencies, are required by law or regulations. Others, such as letters responding to consumers' questions, are provided as a service. FDA documents may also vary in their legal significance; for example, a court document represents the agency's legal position on an issue, and the person signing that document affirms that the information contained in the document is true and/or that he or she is authorized to submit the document. In contrast, the person who signs a letter responding to a consumer's inquiry probably does not intend to have his or her signature affirm that the letter represents FDA's legal position on an issue or to demonstrate his or her authority to issue the letter; he or she may only intend to provide information to the consumer and to identify himself or herself as the person providing the information. It is impractical, therefore, for FDA to evaluate its internal and external communications and to determine, for each type of communication, the significance and meaning of an employee's signature.

As another example, your request for an advisory opinion also asks for "a listing of signature classifications and their meanings" if signatures vary by grade, position, or job classification. FDA cannot reasonably provide a response to this request because, as stated earlier, the meaning and significance of a signature may depend on various factors, such as context, statutory or regulatory requirements, and intent, and is not necessarily dependent on an employee's grade, position, or job classification. To illustrate, regulations issued by the Office of Management and Budget (OMB) require a "Senior Official" or a designee to make certain certifications for Paperwork Reduction Act purposes (see 5 CFR 1320.9), and OMB form 83-I requires an agency official to sign a certification statement. In this particular instance, the signature has legal significance and is required by OMB regulations. The signature of the FDA employee, in this instance, is arguably dependent on the employee's position (because of the reference to a "Senior Official" and because, in FDA, certifications are handled in the Office of Information Resources Management), but the employee's grade and job classification are not necessarily relevant to the signature. Yet, if the same employee, in his or her capacity as a supervisor, signs a request for annual leave, the signature does not carry the same legal consequences or significance as the signature on the form 83-I, but is arguably a function of the employee's position and classification, which, in turn, may reflect the employee's grade.

You also ask whether FDA believes that “controls and definitions necessary for defining signatures in the private sector should also be applied to FDA,” but do not identify what those supposed “controls and definitions” are. While we note that you referenced a FDA rule on electronic signatures, that rule’s relevance to your petition is not apparent because your request for an advisory opinion does not suggest that an electronic signature was involved or that there is an issue regarding the significance or importance of electronic signatures, how electronic signatures are defined, or how electronic signatures correspond to written signatures.

In summary, the significance and meaning of an employee’s signature depends on a variety of factors, including, but not limited to, legal authority, statutory and regulatory requirements concerning the document to be signed, the significance of the document in question, and the intent behind the signature. One cannot reasonably respond to your request for an advisory opinion without considering these factors.

Application of § 10.85(a)(2)(iii)

Section 10.85(a)(2)(iii) states, in part, that the Commissioner may deny a request for an advisory opinion if the matter is adequately covered by a regulation. Here, the gravamen of your request for an advisory opinion is that you claim that your supervisors “instructed” you to sign a letter and that you disagreed with the need to send that letter.

As you may know, FDA regulations and the Collective Bargaining Agreement between FDA and the National Treasury Employees Union contain provisions for differences of opinion. FDA regulations at 21 CFR 10.70(b)(2) require employees who are responsible for handling a matter to ensure the completeness of the administrative file for that matter. The administrative file must include “the recommendations and decisions of individual employees, including supervisory personnel, responsible for handling the matter,” and the recommendations and decisions “are to reveal significant controversies *or differences of opinion and their resolution*” (emphasis added).

Similarly, article 5, section 20, paragraph A of the Collective Bargaining Agreement that went into effect on October 1, 1999, states that professional differences of opinion between bargaining unit employees and FDA should be addressed in conformance with 21 CFR 10.70 and 10.75. Article 5, section 20 also describes procedures concerning the administrative file and an employee’s options in the event of a professional difference of opinion.

In this instance, it appears that a difference of opinion between yourself and your supervisors prompted you to request an advisory opinion. Professional differences of opinion should be resolved under 21 CFR §§ 10.70 and 10.75 and

Article 5, section 20 of the Collective Bargaining Agreement rather than through advisory opinions.¹

Application of § 10.85(a)(2)(v)

The Commissioner, under § 10.85(a)(2)(v), may deny a request for an advisory opinion if an advisory opinion “would not be in the public interest.” If we were to consider your request as falling within § 10.85, the agency would deny your request because no public interest is involved. The circumstances leading to your request for an advisory opinion suggested a professional difference of opinion, and, as stated earlier, such matters are more appropriately addressed through 21 CFR §§ 10.70 and 10.75, and article 5, section 20 of the Collective Bargaining Agreement. There is no indication that the recipient of the letter questioned the validity of the signature or the authority to issue the letter, or that the recipient of the letter, or any other person receiving similar documents from FDA, is confused or seeks clarification regarding signatures on those documents. There is no indication that other FDA employees have a substantial interest in this matter that would justify the development and issuance of an advisory opinion. Indeed, your request for an advisory opinion does not even indicate that you signed the letter that was sent to the manufacturer.

Furthermore, given the broad scope of your requests, no public interest would be served by issuing an advisory opinion that considers the significance of an employee’s signature on every document that could be considered an “official agency document” or “signature classifications” and their meanings for the various grades, positions, and job classifications inside FDA. In fact, issuing an advisory opinion could even have a detrimental effect on the agency and, by extension, the public interest because advisory opinions, under existing FDA regulations, are binding on FDA. For example, one request sought a listing of “signature classifications and their meanings” if “signatures vary by grade, position, or job classification.” However, as you know, positions and titles change, offices are reorganized, and the authority to issue documents may be delegated or redelegated. If FDA developed a comprehensive advisory opinion that responded to your request, showing how signatures “vary” by position or job classification, the advisory opinion could limit the agency’s options in delegating authority to other persons to sign certain documents, redelegating authority, and even making office reorganizations. The agency would then be obliged to revise or

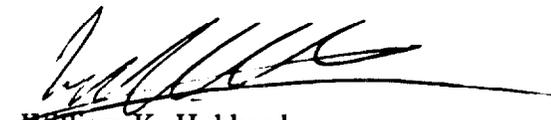
¹ Indeed, according to the Center for Biologics Evaluation and Research, the incident which may have prompted your request for an advisory opinion was handled in accordance with 21 CFR 10.70, and your views were placed in the administrative record. However, for purposes of this response, we will not presume that your request for an advisory opinion is based solely on that one incident.

rescind the advisory opinion in order to delegate or redelegate authority to sign certain documents or update titles and offices to reflect organizational changes.

Conclusion

For the reasons set forth above, the agency finds that your request does not fall within § 10.85 and that, even if the agency were to treat your request as a request for an advisory opinion, the agency would deny your request for an advisory opinion.

Sincerely,

A handwritten signature in black ink, appearing to read 'William K. Hubbard', written over a horizontal line.

William K. Hubbard
Senior Associate Commissioner for
Policy, Planning, and Legislation

cc: Docket No. 98A-0912