Maeder

Comptroller General
of the United States

Washington, D.C. 20548

# Decision

**Matter of:** Neurological Research & Development Group, Inc.

**File:** B-235682

**Date:** September 21, 1989

## DIGEST

1. Protest that awardee failed to comply with Food and Drug Administration regulation requiring registration for "medical device products intended to be delivered to the government" is denied where the record indicates that the medical product is exempt from such registration.

2. Claim of possible patent infringement does not provide a basis for the General Accounting Office to object to an award.

## DECISION

Neurological Research and Development Group, Inc., protests the award of a contract to Sleepwell Mattress under request for proposals (RFP) No. DLA120-88-R-0668, issued by the Defense Personnel Support Center (DPSC), Defense Logistics Agency (DLA) for mattresses. Neurological contends that Sleepwell's product does not satisfy the RFP requirement that it be in compliance with section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. § 360(k) (1982), for medical device products, and that compliance is impossible in this instance because Neurological holds the patent on the mattress required by the solicitation.

We deny the protest.

The RFP was issued for a firm fixed-price contract for 480 four-section support bed mattresses. The RFP indicated that these products were to be manufactured pursuant to Medical Procurement Item Description No. 2, which contained the following regulatory requirement:

> "Federal Food, Drug And Cosmetic Act. If the product covered by this document has been determined by the U.S. Food and Drug Administration [FDA] to be under its jurisdiction,

> the offeror/contractor shall comply . . . with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, and regulations promulgated thereunder. . . ."

The solicitation, as amended, required that each offeror indicate its compliance with or its exemption from section 510(k) of the FFDCA for medical device products intended to be delivered to the government. That statute as implemented at 21 C.F.R. Part 807, Subpart E (1989), essentially requires the manufacturer of a medical device to submit to the FDA information concerning the manufacturing concern and the product it proposes to market. If the medical device is of a certain type, the FDA then renders a decision as to whether the product may be marketed. As evidence of compliance, the solicitation required the offeror to provide the item number, the corresponding premarket notification number and the date of FDA approval or to provide the basis for exemption from the notification procedures.

Best and final offers (BAFOs) were submitted on May 10. On May 19 Neurological received notification that award had been made to Sleepwell as the low-priced offeror. Neurological filed this protest with our Office on May 26.

Neurological contends that the DPSC could not properly award this contract to Sleepwell because Sleepwell was not in compliance with the FFDCA with regard to marketing this device at the time of award. Neurological submits a letter, dated December 14, 1983, from the FDA in which the FDA labels the "Neuropedic Mattress" a "medical device" and on that basis Neurological argues that offerors/contractors are required to obtain a premarket notification approval from the FDA before they can market this device. Neurological argues that Sleepwell could never obtain the required medical device registration because Neurological alleges that it holds the patent on this mattress. Consequently, Neurological argues that Sleepwell is ineligible for award.

In this instance, although the FDA indicated in its December 14 letter that the mattress was considered a medical device, the FDA also expressly indicated that this mattress is a Class 1 device and therefore exempt from the section 510(k) premarket notification requirements. Since a copy of the FDA letter was submitted by the protester with its protest, the protester was clearly apprised of this exemption when it filed its protest. Moreover, Sleepwell indicated in its BAFO that the mattress is exempt from § 510(k) notification because it is a Class 1 device. Finally, as FDA has further explained in response to the

protest, this mattress is a "nonpowered flotation therapy mattress" and thus exempt under 21 C.F.R. § 880.5150 from the section 510(k) notification requirements. Consequently, Neurological's protest on this point has no merit.

Moreover, before award was made to Sleepwell, the FDA completed a quality preaward survey and found that the firm has the capability to furnish a product that is of appropriate quality and that meets the quality requirements of the solicitation. The FDA also found that Sleepwell was in compliance with the FFDCA. A Defense Contract Administration Service survey recommended award based on a satisfactory finding of Sleepwell's technical, production and financial capabilities. Based on these surveys, the contracting officer determined that Sleepwell was responsible.

Finally, Neurological's allegation that other firms may infringe on its patent serves no basis for objection to award. American Cyanamid Co., B-230044 et al., Apr. 7, 1988, 88-1 CPD ¶ 350. We previously have recognized that 28 U.S.C. § 1498 (1982) gives patent holders an adequate and effective remedy for infringement of their patent while saving the government from having its procurements delayed pending litigation of patent disputes. Tracore Dev. Inc., B-231774, B-231778, July 20, 1988, 88-2 CPD ¶ 66; American Cyanamid Co., B-230044 et al., supra.

Accordingly, the protest is denied.

James F. Hinchman
General Counsel