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Reviews




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RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 80 pages. OCLC Number: (OCoLC)535589112 Subject: Medical research personnel -- United States. Excerpt: . . . F i g u r e 1: F D A s D e b a r m e n t P r o c e s s f o r I n d i v i d u a l s FDA staff learn that individual was convicted of a crime and determine whether to pursue debarment (mandatory or permissive) FDA issues a proposal to debar letter, describing the conviction and a misconduct and offering an opportunity for a formal hearing Individual requests a formal hearing Individual does not submit a by the specified date timely request or declines the opportunity for a hearing Request for hearing is: b N o t g r a n t e d G r a n t e d Formal hearing conducted and presiding officer makes recommendation FDA Commissioner or delegate makes decision D e b a r r e d N o t d e b a r r e d Source: GAO. Notes: This figure presents the major steps that could be involved in the debarment proceedings we reviewed. These proceedings involved clinical investigators, sub-investigators, and study coordinators for whom FDA pursued or considered pursuing debarment from May 13, 1992, through September 9, 2008. The number of steps involved for a proceeding can vary depending, for example, on whether the individual chooses to contest the charges by requesting a hearing. All clinical investigators, sub-investigators, and study coordinators whom FDA pursued or considered pursuing for debarment as of the last date of our file review (November 5, 2008) had been convicted of a crime. a Proposal to debar letters specify that if the individual chooses to respond, he or she must submit a written notice of request for a formal...

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