CONTINUING EDUCATION TEST

FDA: The Mission and the Message

For each of the following questions, select the best answer. Then circle the number on the CE Tests Answer Sheet that corresponds to the answer you have selected. Keep a record of your responses so that you can compare them with the correct answers, which will be published in the next issue of the *Journal*. Answers to these test questions should be returned on the Answer Sheet no later than June 1, 1993. Supply your name, address, and VOICE number in the spaces provided on the Answer Sheet. Your VOICE number appears on the upper left hand corner of your *Journal* mailing label. No credit can be recorded without it. A 70% correct response rate is required to receive 0.1 CEU credit for this article. Members participating in the continuing education activity will receive documentation on their VOICE transcript, which is issued in March of each year. Nonmembers may request verification of their participation but do not receive transcripts.

A. *In 1906, Congress approved the Federal Pure Food and Drug act that gave the FDA authority to remove drugs from the marketplace if they were proven impure or unsafe. In 1938, this act was amended requiring applicants to provide* _____.

135. toxicity studies, dosage summaries, and indications for use
136. chemical class, reaction data, and animal testing results
137. toxicity studies, pharmacological research, and efficacy studies
138. 135 and 136
139. all of the above

B. *The 1962 amendments to the Food, Drug and Cosmetic Act require that the product be shown to be effective through adequate and well controlled studies.* _____

140. True
141. False

C. *During all phases of the FDA approval process, alterations of the protocol may take place as long as the FDA is notified of the changes.*

_____

142. True
143. False

D. *The Division of Medical Imaging, Surgical and Dental Drug Products within the FDA is staffed by* _____.

144. radiologists, surgeons, pharmacists, and an administrative officer.
145. physicians, scientists and technologists dedicated to reviewing new drug agents submitted for medical imaging
146. federal employees who review and revise the regulatory policies of the FDA
147. Approximately 7,000 persons who are responsible for the inspection of all facilities where cosmetics and drugs are manufactured

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E. *The lengthy delays in the approval of new radiopharmaceuticals by the FDA is largely caused by* _____.

148. the length and complexity of the FDA's review process
149. the often poor format or substance of data submitted by the sponsors
150. processing backlogs when a reviewer receives several applications within the same time frame
151. all of the above contribute to the lengthy delays in new drug approval and are currently being evaluated for improvement measures

F. *The Kefauver-Harris drug amendments* _____.

152. to the Federal Food, Drug and Cosmetic Act were promulgated by Congress in 1962
153. resulted when increased incidents of a rare birth disorder were traced to a drug used during early pregnancy
154. initiated the requirement that drug efficacy be documented during the clinical phase of testing, *not* retroactively.
155. all of the above

G. *During which phase of the approval process are animal studies performed to determine safety for human trial?*

156. nonclinical phase
157. Phase I
158. Phase II
159. Phase III

H. *During* _____, *efficacy of the new drug is paramount, although safety is still a strong concern.*

160. the nonclinical phase
161. Phase I
162. Phase II
163. Phase III

I. *Dose-range studies and protocol alterations take place during* _____ *of the approval process.*

164. the nonclinical phase
165. Phase I
166. Phase II
167. Phase III

J. *The FDA is responsible for reassuring efficacy and safety in marketed medicinal agents and devices.*

168. True
169. False

K. *The approval process for new drug applications (NDAs) has been criticized for the _____.*

170. data format required for clinical trials
171. redundancy of three-phase clinical trials
172. length of time to review, process, and approve new radiopharmaceuticals
173. complexity of nonclinical phase protocol

L. *The FDA is attempting to improve and streamline the approval process through the following actions.*

174. improved communication
175. efficient tracking of submissions
176. prompt evaluation of submissions at all levels of authority
177. all of the above
178. none of the above

M. *Which of the following statements is not true?*

179. All data is collated upon completion of Phase III trials.
180. IND submissions have a mandated response time of 30 days.
181. Open trials in multiple centers are initiated to assess the ability to replicate data by at least ten, separate, independent investigators.
182. Each submission is now tracked from the time it reaches the document room until final approval or disapproval.

CONTINUING EDUCATION TESTS

Answer Sheet

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Return a copy of this answer sheet to:
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