CONTINUING EDUCATION TEST

Investigational New Drugs: Application, Process and Trial

For each of the following questions, select the best answer. Then circle the reader service card number 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 reader service card no later than March 1, 1991. Supply your name, address, and VOICE number in the spaces provided on the card. 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. *The United States Food and Drug Administration involvement in monitoring the process of bringing a new radiopharmaceutical into commercial use is meant to:*

158. assure profitability.
159. protect the public health.
160. ensure the integrity of copyrights and patents.
161. all of the above.

B. *Until 1962, the FDA had weak requirements on the notification of investigational drugs being tested on humans.*

162. True
163. False

C. *When an investigator participates in a clinical trial for a radiopharmaceutical manufacturer, he/she must complete the FDA 1571 (Investigational New Drug Application) and FDA 1572 (Statement of Investigator Form).*

164. True
165. False

D. *The IND application should include the following information:*

166. composition, source, and manufacturing data for the drug.
167. results of animal studies.
168. information regarding the training and experience of the investigators.
169. detailed outline of the planned investigation.
170. all of the above.

E. *In order to safeguard human subjects in drug experiments, the FDA requires that life-threatening events be reported by the sponsor to the FDA:*

171. promptly in writing.
172. within 3 days in writing and 30 days in person.
173. within 3 working days by phone and written notification within 10 working days.
174. all of the above.
175. none of the above.

F. *Highlights of the IND regulations rewrite include:*

176. annual reports.
177. new format on submission form.
178. less emphasis on human subject's safety.
179. all of the above.
180. 176 and 177 only
181. 177 and 178 only

G. *To accumulate and disseminate new information about already approved drugs, the FDA encourages clinical investigators/sponsors to submit an IND when using a drug approved for another purpose. While an abbreviated application submission may be acceptable, the following may be used to ease the IND process:*

182. the supplier of the approved drug may give permission to use information in the Drug Master File to meet requirements pertaining to the manufacturing of the drug.
183. the supplier may provide information about toxicity, safety, or pharmacology.
184. a study protocol is not necessary.
185. a brief description of the investigator's training, experience, and lab/clinical facilities available may substitute for detailed documentation.
186. 182, 183, and 185 only
187. 182 and 183 only

H. *The clinical trials, Phase III of the IND process, assess the effectiveness of the new drug over a wide range of parameters, and determine the effective dosage. The 1987 IND regulations rewrite made introduction of a new radiopharmaceutical easier by eliminating the need for the sponsor to review, analyze, and report on the clinical use of the investigational new drug.*

188. True
189. False

I. *When can the FDA issue a clinical hold order on an investigator to stop an IND study?*

190. If serious or unreasonable risk occurs to human subjects.
191. If serious flaws of the study design in Phase II or III trials occur.
192. Once submitted, the FDA cannot stop the IND study.
193. none of the above
194. 190 and 191 only

J. *A delay for an IND approval may occur for all except which of the following reasons:*

195. an incomplete IND application (FDA form 1571).
196. failure to fully describe radiation dosimetry calculations, assuming the FDA reviewer is an expert.
197. application submitted in a disordered fashion; questions answered out of order, pages not numbered, and/or supporting documentation unlabeled.
198. submitting extra documentation, for example, the CV of the technologist preparing the radiopharmaceutical.

K. *The FDA will provide to the investigator the required informed consent document necessary for the clinical subject to sign.*

199. True
200. False

L. *A facility's in-house IND activities may need the Institutional Review Board to approve the informed consent documentation.*

201. True
202. False

M. *A facility's Radiation Safety Committee must approve the total radiation exposure to the staff and the subjects involved in the IND study.*

203. True
204. False

N. *The Hospital Research Committee may rule on the merit of an IND study as well as determine whether it will be funded or not.*

205. True
206. False

Answers to CE Article Tests, September 1990

The Continuing Education article "Dipyridamole Thallium Imaging," by Bradley K. Pounds, Warren H. Moore, Eric J. Ladwig, Julie S. Blust, Michael G. Viguet, Michael J. Blust, and Ramesh D. Dhekne was accompanied by a CE article test. The correct answers are:

A. 104	D. 112	G. 128	J. 144
B. 108	E. 117	H. 134	K. 147
C. 111	F. 122	I. 140	

The answers to the CE article test on "Radioimmunotherapy with Monoclonal Antibodies," by Cathleen M. Suey, Gerald L. DeNardo, Sally J. DeNardo, and Allan Gobuty are:

A. 150	E. 167	I. 186	M. 202
B. 154	F. 169	J. 187	N. 204
C. 157	G. 176	K. 194	O. 206
D. 161	H. 183	L. 197	