IJARSCT



International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)

International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal

Volume 3, Issue 1, December 2023

Review on Food and Drug Administration

Pratiksha. K. Budhbaware, Rashmi Sonkusare, Chaitalee Girde, Prajwal Wankhade

New Montfort Institute of Pharmacy, Ashti, Wardha, Maharashtra, India pratikshabudhabaware49@gmail.com

Abstract: Clinical trial evidence used to support drug approval is typically the only information on benefits and harms that patients and clinicians can use for decision-making when novel cancer therapies become available. Various evaluations have raised concern about the uncertainty surrounding these data, and a systematic investigation of the available information on treatment outcomes for cancer drugs approved by the US Food and Drug Administration (FDA) is warranted. Indeed drug delivery system should be designed to provide a therapeutic agent in the needed amount, at the right time to the proper location in the body, in a manner that optimizes efficacy, increases compliance and minimizes side effects. A well designed controlled drug delivery system can overcome some of problems of conventional therapy and enhance therapeutic efficacy of the given drug. The US Food and Drug Administration (FDA) oversees safety and efficacy of a broad spectrum of medical products (ie, drugs, biologics, and devices) under the auspices of federal legislation and agency regulations and policy.

Keywords: Expanded access, Immediately life-threatening Disease, Industry, Investigator, Sponsor.

REFERENCES

- [1]. Federal Food and Drug Act of 1906 (F&DA), P.L. 59-384, 1906.
- [2]. Federal Food, Drug, and Cosmetic Act (FFDCA), P.L. 75-717, 1938. The FFDCA included a provision to repeal the F&DA.
- [3]. US Food and Drug Administration. Frequently asked questions. Available at http://www.fda.gov/opacom/faqs/faqs.html. Accessed 31 March 2000
- [4]. Linda Horton, Director, International Policy, United States Food and Drug Administration (FDA)
- [5]. FDA approved a total of 535 ANDAs in 2006. This included approved or tentatively approved original ANDAs and those requiring amendments. In contrast, our review included only original ANDAs.
- [6]. FDA (2009). Premarket notification (510k). FDA Web Publication, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmission/PremarketNotification510k/defult.htm Accessed January 15, 2010.
- [7]. FDA (2009). Premarket notification (510k). FDA Web Publication, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmission/PremarketNotification510k/defult.htm>Accessed January 15, 2010
- [8]. FDA (2009). Subpart E-premarket notification procedures. Code of Federal Regulation, 21 CFR 807, http://www.accessedata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5 Accessed March 22, 2010.
- [9]. FDA (2009). Premarket notification (510k). FDA Web Publication,http://www.fda.gov/MedicalDevices/DevicesRegulationandGuidance/HowtomarketYourDevice/ PremarketSubmissions/premarketNotification510k/default.htm Accessed January 15, 2010.
- [10]. federal Food, Drug, and Cosmetic Act (FFDCA), P.L. 75-717, 1938. The FFDCA included a provision to repeal the F&DA.
- [11]. FDA, "Abbreviated New Drug Application (ANDA): Generics," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm.

DOI: 10.48175/568

[12]. https://images.app.goo.gl/QtLcbqtTgFwLJA8M7

ISSN 2581-9429 IJARSCT

IJARSCT



International Journal of Advanced Research in Science, Communication and Technology (IJARSCT)

International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal

Volume 3, Issue 1, December 2023

[13]. FDA, "New Drug Application (NDA): Introduction," http://www.fda.gov/Drugs/DevelopmentApproval Process/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm.

DOI: 10.48175/568

[14]. FFDCA (P.L. 75-717, 1938), §505(c) and (d).

