Sample essay on fda position

Business, Management

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The Food and Drugs Authority in the U. S has a responsibility of ensuring that the country has a safe and reliable drug supply. For a number of years, the general consensus has been that all drugs that FDA approves are effective and safe, and that they treat the relevant illnesses that they are produced for. In delivering its service, FDA has strict rules and laws that act as a guideline to all its operations. These laws cannot be changed to suit individual interests. It is illegal for pharmaceuticals that are unapproved by FDA to be imported into the country as this undermines the duties of the Authority.

Accordingly, the authority is tasked with the duty of ensuring that all drugs used in the territory of America are approved and prescribed to promote effectiveness (Fain et al. 1259). The role the Authority plays in analyzing the quality and effectiveness of a drug cannot be underrated. Without this check, the market would be flooded by substandard drugs from manufacturers that seek to benefit from unsuspecting clients. The Authority takes responsibility whenever a case arises where a citizen uses a drug that is not approved by FDA. Because of this, the Authority should always ensure that all drugs that are imported meet the basic standards. The legality of a drug within America

depends on whether the Authority has approved it or not. Because of the strict rules of the Authority, it would be illegal for Sally to be allowed to import the drug. The Misuse of Drugs Act of 1977 creates an offence for any person importing a drug to America without the approval of FDA (Lang et al. 32). The only way that Sally can have the drug is by travelling out of America and coming back with the drug for personal use as opposed to public use.

Sally's Position

I understand that although FDA has strict rules against importation of unapproved drugs unto America, there are some exceptions under which patients are allowed to import drugs for personal use.

Personally, I think I meet this criteria

The agency has developed a guideline on the Regulation Procedures Manual that addresses personal importations. In this guidance, FDA sets out the priorities in enforcing new drugs that are unapproved. In strict terms, enforcement of importing such drugs is meted to people who do so for commercial purposes and with the intention of defrauding the public. This is because such a move is likely to pose a serious health risk to the public, hence the reason adequate care should be taken. In essence, FDA has exceptions as to when one can be allowed to import drugs that are unapproved for medical reasons.

First, FDA recognizes that one can be allowed to import such drugs for personal use in a case where one had begun treatment in a foreign country using the unapproved drug (Submission et al. 86). When such people move to the United States of America, they will be allowed to receive the drug,

provided they prove that they intend to use it for personal treatment. A person who suffers from a serious problem or condition in which FDA lacks approved treatment is allowed to import such a drug.

In my case, FDA lacks the relevant drug to treat the condition that I am currently suffering from. In such circumstances, I have the right to import the drug and in addition, I believe that FDA is restricted from taking a legal action against me. I also understand that such flexibility is not binding, and, therefore, is to the discretion of FDA (Submission et al. 86). However, based on all the facts that I have provided, I should nevertheless be allowed to import the drug because FDA does not have an approved method of dealing with such conditions in the United States of America.

Letter from FDA to Sally

Dear Sally,

Please understand that for a new drug to be used in the United States of America, it must go through the Investigational New Drug (IND) approval. During this process, agencies seek to determine whether the drug (product) is safe for human use. It is also during this process that a determination is made as to whether the product justifies commercial development within the stipulated rules (Stringer, 748).

Agents of a drug company that seeks approval from FDA to sell it in United States must subject the drug to various tests. First, the drug is subjected to laboratory tests to determine its components and whether it has potential risks (Stringer, 748). The drug is then subjected to animal tests to determine the impact it has on living organisms. After the tests on animals, the drug is then tested on humans to determine the effect it has. It is during this test

that FDA determines the safety and effectiveness of the drug in treating or diagnosing a certain condition.

Drug tests are followed by the company in question sending an application to FDA. This application is referred to New Drug Application (NDA). However, not all drugs are approved through NDA. Drugs that are biological in nature seek approval through the Biological License Application. Whichever method the company may decide to use, the application must meet some basics. It has to provide the test results of the drug. The company should provide manufacturing information to ensure it is properly used. It is also important for the company to provide the drug's proposed label (Stringer, 751).

These are the procedures that are in place and therefore, they must all be followed. If you met this criteria then you may be allowed to import the drug.

Works Cited

Fain, Kevin, and G. Caleb Alexander. " Are Food and Drug Administration prescription drug safety plans working? A case study of isotretinoin." Pharmacoepidemiology and Drug Safety 22. 12 (2013): 1258-1262. Print.

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