



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0473]

Human Immunodeficiency Virus Patient-Focused Drug Development and Human Immunodeficiency Virus Cure Research; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of public meeting entitled "Human Immunodeficiency Virus (HIV) Patient-Focused Drug Development and HIV Cure Research," published in the Federal Register of May 21, 2013 (78 FR 29755). In that notice, FDA requested public comment regarding patients' perspective on current approaches to managing HIV, symptoms experienced because of HIV or its treatment, and issues related to HIV cure research. FDA is reopening the comment period to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments to the docket by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1170,

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of May 21, 2013 (78 FR 29755), FDA announced the notice of public meeting entitled "HIV Patient-Focused Drug Development and HIV Cure Research." In that notice, FDA requested public comment on specific questions regarding patients' perspective on current approaches to managing HIV, symptoms experienced because of HIV or its treatment, and issues related to HIV cure research. Interested persons were given until July 14, 2013, to comment on the questions. The Agency is reopening the comment period until [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] to allow interested persons additional time to submit comments.

II. Specific Questions for Public Comment

As part of Patient-Focused Drug Development, FDA is gathering input from HIV patients and patient advocates on current approaches to managing HIV, symptoms experienced because of HIV or its treatment, and issues related to HIV cure research. FDA is interested in receiving patient input that addresses the following questions.

Topic 1: Patients' perspective on current approaches to managing HIV and on symptoms experienced because of HIV or its treatment

1. What are you currently doing to help manage your HIV and any symptoms you experience because of your condition or other therapies? (Examples may include prescription medicines, over-the-counter products, and nondrug therapies such as diet modification.)

- a. What specific symptoms do your therapies or treatments address?
 - b. How long have you been on treatment and how has your treatment regimen changed over time?
2. How well does your current treatment regimen treat any significant symptoms of your condition?
- a. How well have these treatments worked for you as your condition has changed over time?
 - b. Are there symptoms that your current regimen does not address at all or does not treat as well as you would like?
3. What are the most significant downsides to your current therapies or treatments, and how do they affect your daily life? (Examples of downsides could include bothersome side effects, physical change to your body because of treatment, going to the hospital for treatment.)
4. Of all the symptoms that you experience because of your condition or because of your therapy or treatment, which one to three symptoms have the most significant impact on your life? (Examples could include diarrhea, insomnia, difficulty concentrating, etc.)
- Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene, driving, etc.)
5. Assuming there is currently no complete cure for your condition, what specific things would you look for in an ideal therapy or treatment to manage your condition?

Topic 2: Patients' perspectives on HIV Cure Research

1. What do you believe are the benefits of participating in an HIV cure research study?
2. What would motivate you to participate or to not participate in an HIV cure research study?
3. What risks would you find unacceptable for participating in an HIV cure research study and why? (Examples of risks that may be associated with participation in an HIV cure research study include common side effects such as nausea and fatigue, and less common but serious adverse events such as blood clots, infection, seizures, and cancer.)
4. In certain HIV cure research studies, you would be asked to stop any other HIV medications that you are currently taking. How would this affect your decision whether to participate in an HIV cure research study?
5. The process of informed consent is an important way for the researchers to communicate the purpose of an HIV research study, as well as its expected benefits and potential risks, so that people can make an informed decision whether to participate in the study.
 - a. How should the informed consent clearly communicate to you the purpose of an HIV cure research study, particularly when a study is designed only to provide scientific information that could guide future research and development of treatments?
 - b. How should the informed consent clearly communicate to you the potential benefits of an HIV cure research study? In particular, how should the informed

consent describe benefit when we do not think that participants in the study may gain any direct health benefits?

- c. How should informed consent communicate clearly to you the potential risks of participating in an HIV cure research study? In particular, how should the informed consent describe a study if there is very limited understanding about how the medications or interventions may affect participants or what are the potential risks of those interventions or medications?
 - d. Is there any other information that you would find helpful when deciding whether to enter an HIV cure research study?
6. What else do you want FDA to know about HIV Cure Research from your perspective?

III. How to Submit Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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