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American Red Cross

December 26, 2018

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Submitted via http://www.regulations.gov

Re: Docket No. FDA–2018-D-3197, "Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus" draft guidance, September 2018

Dear Dockets Manager:

AABB, America's Blood Centers (ABC) and the American Red Cross (ARC) are jointly submitting comments to the Food and Drug Administration (FDA) on the September 2018 draft guidance, "Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Draft Guidance for Industry" (the September 2018 HCV draft guidance). Members of the AABB's Transfusion Transmitted Diseases Committee, and representatives from ARC and ABC have prepared these comments.

As noted in the 2018 HCV draft guidance, when the Chiron RIBA™ HCV 3.0 (HCV RIBA) assay was discontinued in February 2013, blood establishments followed information posted on FDA's website regarding the use of licensed HCV NAT tests labeled with a "limited supplemental claim," to confirm HCV infection for donations testing repeatedly reactive donations using the anti-HCV screening test. No additional information was provided for further testing of donations found repeatedly reactive on an anti-HCV screening test and nonreactive on HCV NAT. In the May 2015 final rule, FDA revised 21 CFR 610.40(e) to require further testing using an approved supplemental test *when one is available*.

We find the 2018 HCV draft guidance to be consistent with current practices for HCV testing

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implemented by blood establishments to protect blood safety in the absence of the HCV RIBA. We support the recommendations for use of a licensed HCV NAT test (labeled with the supplemental indication and according to the manufacturer's instructions) for further testing of donations found repeatedly reactive for anti-HCV on a licensed donor screening test. We support notification of donors who are deferred based on the testing results, and the lookback requirements of 21 CFR 610.47, including notification of consignees and transfusion recipients, and proper inventory management to quarantine and/or destroy blood components when indicated.

In the final guidance, please clarify the opening sentence in Section III which states:

> *"We recommend further testing of donations, including autologous donations, which are repeatedly reactive for anti-HCV on a licensed donor screening test,* ***using a licensed HCV NAT test****…"*

Based on mixed interpretations of FDA's intent, please clarify if further testing must be performed using HCV ID-NAT. This question arises from the interpretation by some that, if a licensed NAT using multiplex reagents for donations screened in a pool that is performed simultaneously with licensed anti-HCV is negative, then no further NAT is required.

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through the development and delivery of standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers. AABB members are located in more than 80 countries and AABB accredits institutions in over 50 countries.

Founded in 1962, ABC is North America's largest network of community-based, independent blood programs. The network operates more than 600 blood donor centers providing over half of the U.S., and a quarter of the Canadian blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.

The ARC shelters, feeds and provides emotional support to victims of disasters; supplies about 40 percent of the nation's blood; teaches skills that save lives; provides international humanitarian aid; and supports military members and their families. The Red Cross is a not-for-profit organization that depends on volunteers and the generosity of the American public to perform its mission. About 5.6 million units of whole blood are collected from roughly 3.3 million Red Cross volunteer donors, separated into 8 million transfusable blood products and supplied to approximately 2,700 hospitals and transfusion centers across the country for patients in need.

Thank you for the opportunity to offer these comments. We look forward to continuing to work with the FDA on patient and donor safety initiatives. Questions concerning these comments may be directed to scarayiannis@aabb.org.

Sincerely,

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