Blood Pressure and Pulse Donor Eligibility Requirements – Compliance Policy

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Draft Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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I. INTRODUCTION

This guidance addresses the regulatory requirements for determining donor eligibility that apply to establishments that collect blood and blood components (blood establishments) for transfusion or for further manufacturing use, including Source Plasma. In the final rule dated May 22, 2015 (Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use (donor eligibility rule)) (Ref. 1), FDA (we) amended the regulations applicable to blood establishments for determining donor eligibility and testing blood and blood components. The revised requirements were implemented in order to assure the safety of the blood supply and to protect donor health. The donor eligibility rule became effective on May 23, 2016.

FDA has developed this guidance in response to feedback from blood establishments regarding the donor eligibility requirements for blood pressure and pulse in Title 21 of the Code of Federal Regulations 630.10 (21 CFR 630.10) and the corresponding requirements for medical supervision in 21 CFR 630.5. This guidance describes the circumstances in which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain regulations for determining the eligibility of blood donors with blood pressure or pulse measurements outside of the specified limits.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

In November 2009, FDA held a Blood Products Advisory Committee (BPAC or Committee) meeting to seek the Committee's advice on, among other things, whether available data support the utility of obtaining predonation blood pressure and pulse measurements as predictors of the risk of adverse response to donation (Ref. 2). The majority of the Committee responded that data did not establish predonation blood pressure as a predictor of risk of an adverse response; the Committee was divided on whether pulse measurement was a predictor of adverse reactions. However, many members of the committee stated that pulse and blood pressure measurement should be retained as part of the donor assessment. The committee expressed concern for the health of donors with blood pressure outside the specified limits, noting the lack of data on the safety of blood donations by individuals with unusually high or low blood pressure. Several members raised concerns of an association between high pulse rates and increased rates of vasovagal reactions. However, it was noted that data have shown that donors with low pulse rates are not at increased risk of reactions. This finding likely reflected standard practice at the time to accept donors with low pulse (<50 bpm) only if they reported being otherwise healthy athletes.

In May 2015, FDA published the donor eligibility rule and finalized the requirements for blood pressure and pulse limits (Ref. 1). The regulations for blood pressure and pulse limits allow for donation by donors with measurements outside the specified limits if, among other things, the responsible physician determines that their health would not be adversely affected by donating (21 CFR 630.10(f)(2); 21 CFR 630.10(f)(4)).

Current FDA donor eligibility regulations require that on the day of donation and before collection, a donor's systolic blood pressure must not measure above 180 mm of mercury or below 90 mm of mercury, and diastolic blood pressure must not measure above 100 mm of mercury or below 50 mm of mercury (21 CFR 630.10(f)(2)). A donor with measurements outside these limits may be permitted to donate only when the responsible physician examines the donor and determines and documents that the health of the donor would not be adversely affected by donating (21 CFR 630.10(f)(2)). This examination and determination must not be delegated (21 CFR 630.5(b) and (c)).

In addition, on the day of donation and before collection, a donor's pulse must be regular and between 50 and 100 beats per minute (bpm) (21 CFR 630.10(f)(4)). If pulse is irregular or the rate falls outside the specified limits, the donor may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating (21 CFR 630.10(f)(4)). This determination must not be delegated but may be performed by telephonic or other offsite consultation (21 CFR 630.5(b) and (c)).

III. DISCUSSION

Following publication of the donor eligibility rule, FDA approved standard operating procedures (SOPs) from individual blood establishments that allowed for a one-time determination by the

responsible physician that the health of the donor would not be adversely affected by donating for athletic donors with a pulse rate less than 50 beats per minute (bpm). Based on this one-time determination by the responsible physician, the donor would not be disqualified on the basis of such pulse rate for future donations.

However, FDA continues to receive feedback from stakeholders that the requirement in 21 CFR 630.10(f)(4) for the responsible physician to make a determination of the donor's health for donors with pulse measurements less than 50 bpm or donors with irregular pulse and the requirement in 21 CFR 630.10(f)(2) for the responsible physician to examine and make a determination of the donor's health for donors with blood pressure measurements outside the specified limits are burdensome and not necessary to protect donor health. In addition, stakeholders have reported the requirements result in the deferral of many healthy blood donors because the responsible physician is often not available for the examination or to make the determination of health.

FDA has considered these comments and agrees that some flexibility is warranted with respect to the responsible physician's medical oversight. Specifically, we agree that having a responsible physician examine a donor with blood pressure measurements outside the specified limits is not always necessary to protect donor health. While blood pressure measurements outside the specified limits may indicate that a donor is not healthy, donor health is adequately protected when the responsible physician makes a medical determination by telephonic or other offsite consultation that the donation will not adversely affect the health of the donor and documents that determination.

Further, we agree that for individuals with a pulse measurement below 50 bpm who report being healthy athletes and for individuals with an irregular pulse, consultation with the responsible physician is not always necessary to protect donor health. Specifically, donor health can be adequately protected when individuals with pulse measurements below 50 bpm who report being healthy athletes are considered eligible without consultation with the responsible physician. Further, while an irregular pulse may indicate that a donor is not healthy, donor health can be adequately protected when individuals with an irregular pulse are considered eligible without consultation with the responsible physician.

IV. DONOR BLOOD PRESSURE AND PULSE ELIGIBILITY REQUIREMENTS – COMPLIANCE POLICY

This guidance describes the circumstances in which FDA does not intend to take regulatory action regarding requirements to determine donor eligibility based on blood pressure and pulse measurement.

A. Blood Pressure (21 CFR 630.10(f)(2))

For a donor with blood pressure measurements outside of the specified limits (90-180 mm Hg systolic or 50-100 mm Hg diastolic), we do not intend to take regulatory action

with respect to the requirement in 21 CFR 630.10(f)(2) that the donor may be permitted to donate only when the responsible physician examines the donor, when the responsible physician conducts a telephonic or other offsite consultation, and determines and documents that the health of the donor would not be adversely affected by donating. Consistent with 21 CFR 630.5(b)(1)(i)(A) and 21 CFR 630.5(c)(1)(i)(A)(1), the responsible physician must not delegate this determination of the donor's health.

B. Pulse (21 CFR 630.10(f)(4)) and Medical Supervision (21 CFR 630.5(b)(1)(i)(B) and 21 CFR 630.5(c)(1)(i)(A)(2))

For a donor with a pulse measurement below 50 bpm who self-reports being a healthy athlete, we do not intend to take regulatory action with respect to the requirement in 21 CFR 630.10(f)(4) that the donor may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating, and the requirements in 21 CFR 630.5(b)(1)(i)(B) and 21 CFR 630.5(c)(1)(i)(A)(2) that the responsible physician must not delegate this determination of the donor's health. We intend to apply this compliance policy when the blood establishment establishes, maintains and follows SOPs[1] that:

- are approved by the responsible physician of the blood establishment; and,
- allow for donation by a donor with a pulse measurement below 50 bpm who self-reports being a healthy athlete without consultation with the responsible physician.

For a donor with an irregular pulse, we do not intend to take regulatory action with respect to the requirement in 21 CFR 630.10(f)(4) that the donor may be permitted to donate only when the responsible physician determines and documents that the health of the donor would not be adversely affected by donating, and the requirements in 21 CFR 630.5(b)(1)(i)(B) and 21 CFR 630.5(c)(1)(i)(A)(2) that the responsible physician must not delegate this determination of the donor's health. We intend to apply this compliance policy when the blood establishment establishes, maintains, and follows SOPs that:

- are approved by the responsible physician of the blood establishment; and,
- define medical criteria for donation by a donor with an irregular pulse without consultation with the responsible physician.

[1] Note: Blood establishments must establish, maintain and follow written procedures for all steps in the collection of blood and blood components, including criteria used to determine donor eligibility (see 21 CFR 606.100(b)).

V. IMPLEMENTATION

Licensed blood establishments must report changes to their SOPs made in accordance with this guidance as Changes Being Effected (CBE) supplements under 21 CFR 601.12(c)(5). See 21 CFR 601.12(a)(3).

VI. REFERENCES

1. Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, Final Rule, May 22, 2015, 80 FR 29841, *available at*: https://www.federalregister.gov/documents/2015/05/22/2015-12228/requirements-for-blood-and-blood-components-intended-for-transfusion-or-for-further-manufacturing.

2. FDA Blood Products Advisory Committee, November 17, 2009, Transcript *available at:* https://wayback.archive-it.org/7993/20170406174346/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm276284.htm.