NDA 219083

NDA APPROVAL

Cytokinetics, Incorporated
Attention: Rachel E. Melman, MBS, RAC
Executive Director, Regulatory Affairs
350 Oyster Point Blvd
South San Francisco, CA 94080

Dear Rachel Melman:

Please refer to your new drug application (NDA) received September 26, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Myqorzo (aficamten) tablets.

We acknowledge receipt of your major amendment dated March 28, 2025, which extended the goal date by three months.

This NDA provides for the use of Myqorzo (aficamten) for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide) as well as annual reportable changes not included in the enclosed labeling. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As.*[2]

---

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

The SPL will be accessible via publicly available labeling repositories. We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 219083**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Myqorzo (aficamten) tablets shall be 30 months from the date of manufacture when stored at 20°C to 25°C.

ADVISORY COMMITTEE

Your application for Myqorzo was not referred to an FDA advisory committee because the application did not raise significant public health questions on the role of the drug in the diagnosis, cure, mitigation, treatment, or prevention of a disease.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt from this requirement.

POSTMARKETING REQUIREMENTS UNDER 505(o)

Section 505(o)(3) of the FDCA authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA makes certain findings required by the statute.

We have determined that an analysis of spontaneous postmarketing adverse events reported under subsection 505(k)(1) of the FDCA will not be sufficient to identify unexpected serious risks of Myqorzo on pregnancy and maternal complications, as well as adverse effects on the developing fetus, the neonate, and the infant exposed to aficamten during pregnancy. Also, analysis of spontaneous postmarketing data is insufficient to identify an unexpected serious risk associated with the presence of aficamten in human breast milk and ascertain the clinical importance for the infant exposed via breast milk. Furthermore, the active postmarket risk identification and analysis system as available under section 505(k)(3) of the FDCA will not be sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, FDA has determined that you are required to conduct the following studies:

4900-1 A worldwide descriptive study that collects prospective and retrospective data in women exposed to Myqorzo during pregnancy to assess risks of pregnancy and maternal complications, and adverse effects on the developing fetus, the neonate, and the infant. Assess infant outcomes through at least the first year of life. The minimum number of patients will be specified in the protocol.

The timetable you submitted on November 11, 2025, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	06/2026
Final Protocol Submission:	12/2026
Interim study report:	12/2029 (may be incorporated in the NDA Annual Report)
Interim study report:	12/2033 (may be incorporated in the NDA Annual Report)
Study Completion:	12/2036
Final Report Submission:	09/2037

4900-2 A milk-only lactation study in lactating women who have received Myqorzo to measure concentrations of aficamten in breast milk using a validated assay. Assess the effects on the breastfed infant, if available, based on study population.

The timetable you submitted on November 11, 2025, states that you will conduct this study according to the following schedule:

Draft Protocol Submission:	06/2026
Final Protocol Submission:	12/2026
Study Completion:	12/2028

Final Report Submission: 06/2029

FDA considers the term *final* to mean that the applicant has submitted a protocol, the FDA review team has sent comments to the applicant, and the protocol has been revised as needed to meet the goal of the study or clinical trial.[3]

Submit clinical protocol(s) to your IND 138814 with a cross-reference letter to this NDA. Submit nonclinical and chemistry, manufacturing, and controls protocols and all final report(s) to your NDA. Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate:

REQUIRED POSTMARKETING PROTOCOL UNDER 505(o), REQUIRED POSTMARKETING FINAL REPORT UNDER 505(o), REQUIRED POSTMARKETING CORRESPONDENCE UNDER 505(o).

Submission of the protocol(s) for required postmarketing observational studies to your IND is for purposes of administrative tracking only. These studies do not constitute clinical investigations pursuant to 21 CFR 312.3(b) and therefore are not subject to the IND requirements under 21 CFR part 312.

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Section 506B(a)(1) of the FDCA, as well as 21 CFR 314.81(b)(2)(vii) requires you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

FDA will consider the submission of your annual report under section 506B(a)(1) and 21 CFR 314.81(b)(2)(vii) to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in 505(o) and 21 CFR 314.81(b)(2)(vii). We remind you that to comply with 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to submit an annual report for studies or clinical trials required under 505(o) on the date required will be considered a violation of FDCA section 505(o)(3)(E)(ii) and could result in enforcement action.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the FDCA authorizes FDA to require the submission of a risk evaluation and mitigation strategy (REMS), if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks.

[3] See the guidance for Industry *Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act (October 2019).* https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

In accordance with section 505-1 of FDCA, we have determined that a REMS is necessary for Myqorzo to ensure the benefits of the drug outweigh the risk of heart failure due to systolic dysfunction.

Your proposed REMS must include the following:

Elements to assure safe use: Pursuant to 505-1(f)(1), we have determined that Myqorzo can be approved only if elements necessary to assure safe use are required as part of the REMS to mitigate the risk of heart failure due to systolic dysfunction listed in the labeling of the drug.

Your REMS includes the following elements to mitigate this risk:

- Healthcare providers have particular experience or training, or are specially certified
- Pharmacies, practitioners, or health care settings that dispense the drug are specially certified
- The drug is dispensed to patients with evidence or other documentation of safe-use conditions
- Each patient using the drug is subject to certain monitoring

Implementation System: The REMS must include an implementation system to monitor, evaluate, and work to improve the implementation of the elements to assure safe use (outlined above) that require: pharmacies, practitioners, or health care settings that dispense the drug be specially certified and the drug be dispensed to patients with documentation of safe use conditions.

Your proposed REMS, submitted on March 28, 2025, amended and appended to this letter, is approved.

The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

Your REMS must be fully operational before you introduce Myqorzo into interstate commerce.

The REMS assessment plan must include, but is not limited to, the following:

For each metric, provide the two previous, current, and cumulative reporting periods (where applicable) unless otherwise noted.

Program Implementation and Operations

1. REMS Implementation (for the first REMS assessment only)
    a. Date of first commercial availability of Myqorzo
    b. For each participant (healthcare providers, pharmacies, patients), the date they could become certified or enrolled

   c. Date when the Myqorzo Call Center was established and fully operational
   d. Date when the Myqorzo REMS website became live and fully operational
2. REMS Certification and Enrollment Statistics
   a. Healthcare providers
      i. Number of newly certified healthcare providers and number of active healthcare providers (i.e., who have prescribed Myqorzo at least once during the reporting period) stratified by specialty (e.g., Cardiology, Internal/General Medicine, Other).
      ii. Total number of REMS support staff
         1. Number of certified healthcare providers with more than four linked REMS support staff
      iii. Number of newly designated REMS healthcare provider delegates and total number of designated REMS healthcare provider delegates, stratified by credentials (e.g., medical doctor, physician assistant, nurse practitioner), and clinical specialty
   b. Pharmacies
      i. Number of newly certified pharmacies
      ii. Number of active pharmacies (i.e., that have dispensed Myqorzo at least once during the reporting period)
   c. Patients
      i. Number of newly enrolled patients and number of active patients (i.e., who have received at least one dispense of Myqorzo during the reporting period) stratified by age ranges of less than 18, 18-40, 41-60, 61 years and older. Provide the minimum and maximum age of enrolled patients.
   d. Wholesalers-distributors
      i. Number of newly contracted wholesalers-distributors and number of active wholesalers-distributors (i.e., that have shipped Myqorzo at least once during the reporting period)
3. Drug Utilization
   a. The total number of REMS Dispense Authorization (RDA) requests received
   b. The number of RDA requests received and authorized, stratified by:
      i. Healthcare provider specialty
      ii. Patient age
   c. The number of RDA requests received and denied (not authorized), stratified by:

i. Reasons and number of denials (numerator) divided by all denials (denominator)
    1) Healthcare provider not certified
    2) Pharmacy not certified
    3) Patient not enrolled
    4) No valid documentation of authorization to receive Myqorzo
        a. No **Patient Enrollment Form**
        b. No **Patient Monitoring Form**
        c. Dose mismatch between RDA request and **Patient Enrollment Form**
            i. RDA dose exceeds authorized dose on form
            ii. RDA dose is lower than authorized dose on form
        d. Dose mismatch between RDA request and allowable doses based on **Patient Monitoring Form**
            i. RDA dose exceeds allowable dose based on form
            ii. RDA dose is lower than allowable dose based on form

d. Number of Myqorzo dispenses with an RDA
e. Total number of Myqorzo dispenses (including those with an RDA and those without an RDA); provide the data source
f. Number of Myqorzo dispenses with an RDA (numerator) divided by total number of Myqorzo dispenses (denominator)
g. Number of prescriptions for unique healthcare providers for which an RDA was requested in the reporting period
h. Number of unique patients who received at least one RDA during the reporting period, stratified by age

4. Treatment Overrides
    a. Total number of treatment overrides requested during the reporting period
        i. Number of treatment overrides granted
        ii. Number of treatment overrides denied
    b. Reasons and number of treatment overrides granted during the reporting period

   c. Number of patients with more than one treatment override granted within a 12-month period

5. REMS Compliance

   a. Noncompliance

      i. A copy of the noncompliance plan, including the criteria for noncompliance for healthcare providers, pharmacies, and wholesalers-distributors, actions taken to address noncompliance for each case, and which events lead to de-certification from the Myqorzo REMS

   b. Audits

      i. A copy of the audit plan for pharmacies and wholesalers-distributors

      ii. Report of audit findings for each participant (i.e., pharmacies and wholesalers-distributors)

      iii. Number of audits expected, and the number of audits performed

      iv. Documentation of REMS participant compliance with REMS requirements, including but not limited to:

         1. Documentation of completion of training for relevant staff

         2. Documentation of processes and procedures in place for complying with the Myqorzo REMS

            a. Pharmacies must agree to maintain records of dispensing information to become certified in the REMS

            b. Auditors will evaluate a representative sample of the Myqorzo pharmacy dispensing data to confirm that an RDA was obtained prior to dispensing, in alignment with REMS compliance requirements

      v. Verification for each audited certified pharmacy that each designated Authorized Representative remains the same. If different, and there is no other certified Authorized Representative, document that the pharmacy has certified with the name and contact information for the new Authorized Representative

      vi. Number and types of deficiencies noted for each group of audited participants as a percentage of audited participants

      vii. For participants with deficiencies noted, the number that successfully completed a Corrective and Preventative Action (CAPA) plan as a percentage of those for which a CAPA plan was requested

viii. For any participants who did not complete the CAPA Plan, a description of actions taken

c. Healthcare provider noncompliance (for each noncompliance event, the source of the report, a description of the event, the root cause analysis of the event, and corrective actions taken)

i. Number of healthcare providers who were noncompliant with the Myqorzo REMS requirements. Provide as a percentage of active healthcare providers

ii. Number of healthcare providers who were decertified and reasons for de-certification, also provided as a percentage of active healthcare providers. Include if any healthcare providers were recertified

d. Pharmacies (for each noncompliance event, the source of the report, a description of the event, the root cause analysis, and corrective actions taken)

i. Number of pharmacies for which noncompliance with the Myqorzo REMS is detected

ii. Number of noncertified pharmacies that dispensed Myqorzo

iii. Number of Myqorzo prescriptions dispensed by noncertified pharmacies

iv. Number of Myqorzo prescriptions dispensed that were written by non-certified healthcare providers

v. Number of Myqorzo prescriptions dispensed to unenrolled patients

vi. Number of Myqorzo prescriptions dispensed to patients based on a prescription from a noncertified healthcare provider

vii. Number of times a Myqorzo prescription was dispensed because a certified pharmacy bypassed the Myqorzo REMS RDA processes

viii. Number of pharmacies decertified, reasons for decertification, and actions to address noncompliance

ix. Number of Myqorzo dispenses without an RDA

e. Wholesalers-distributors (for each noncompliance event, the source of the report, a description of the event, the root cause analysis, and corrective actions taken)

i. Number of contracted wholesalers-distributors for which noncompliance with the Myqorzo REMS is detected

ii. Number of wholesalers-distributors suspended from distributing, reasons for the suspension, and actions to address noncompliance

iii. Number of times Myqorzo was distributed to a noncertified pharmacy

REMS Infrastructure and Performance

6. REMS Website
    a. Number of total visits and unique visits to the REMS website
    b. Number and type of REMS materials downloaded for each material
7. REMS Call Center Reports
    a. Number of contacts by participant type (patient, healthcare provider, REMS support staff, REMS healthcare provider delegate, pharmacy, wholesaler-distributor, other)
    b. Summary of reasons for calls (e.g., enrollment question) and participant type (patient, healthcare provider, REMS support staff, pharmacy, other). Limit the summary to the top five reasons for calls by each participant group
    c. If the summary reason for the call(s) indicates a complaint, include details on the nature of the complaint(s) and whether the caller indicated potential REMS burden or patient access issues

Safe Use Behaviors

8. Patient Monitoring Forms
    a. Number of **Patient Monitoring Forms** expected, received, and outstanding
    b. Number of unique patients who had a **Patient Monitoring Form** submitted for whom the healthcare provider confirmed reviewing the echocardiogram results
    c. Number of unique patients who had a **Patient Monitoring Form** submitted for whom the healthcare provider authorized treatment
    d. Number of **Patient Monitoring Forms** on which the healthcare provider indicated that the patient experienced a clinical heart failure event requiring clinical intervention or hospitalization since the last submitted form
    e. Number of **Patient Monitoring Forms** on which the healthcare provider indicated the patient's LVEF in the following ranges:
        i. ≥55%
        ii. <55% and ≥50%
        iii. <50% and ≥40%
        iv. <40%

f. Number of patients who were not authorized to continue treatment as indicated on the **Patient Monitoring Form**

g. Number of **Patient Monitoring Forms** on which the allowable dose matches the dose listed in the corresponding RDA request

h. Number of **Patient Monitoring Forms** on which the allowable dose does *not* match the dose listed in the corresponding RDA request

9. Healthcare Provider Knowledge Assessments

   a. Number of completed **Healthcare Provider Knowledge Assessments**, including the method of completion and number of attempts to complete

   b. A summary of the most frequently missed **Healthcare Provider Knowledge Assessment** questions

   c. A summary of potential comprehension or perception issues identified with the **Healthcare Provider Knowledge Assessment**

Overall Assessment of REMS Effectiveness

10. The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether one or more such goals or such elements should be modified.

If the information provided in an assessment is insufficient to allow FDA to determine whether the REMS is meeting its goals or whether the REMS must be modified, FDA may require the submission of a new assessment plan that contains the metrics and/or methods necessary to make such a determination. Therefore, FDA strongly recommends obtaining FDA feedback on the details of your proposed assessment plan to ensure its success. To that end, we recommend that methodological approaches, study protocols, other analysis plans and assessment approaches used to assess a REMS program be submitted for FDA review as follows:

Submit your proposed audit plan and non-compliance plan for FDA review within 30 days of this letter.

Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 219083 REMS ASSESSMENT METHODOLOGY
(insert concise description of content in bold capital letters, e.g.,
ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A). This assessment should include:

a) An evaluation of how the benefit-risk profile will or will not change with the new indication;

b) A determination of the implications of a change in the benefit-risk profile for the current REMS;

c) *If the new, proposed indication for use introduces unexpected risks*: A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.

d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use*: A statement about whether the REMS was meeting its goals at the time of the last assessment and if any modifications of the REMS have been proposed since that assessment.

e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.

f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including*: Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing a REMS modification*, provide a rationale for why the REMS does not need to be modified.

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

We remind you that section 505-1(f)(8) of FDCA prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 219083 REMS ASSESSMENT

or

NEW SUPPLEMENT FOR NDA 219083/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 219083/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION

or

NEW SUPPLEMENT FOR NDA 219083/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING CHANGES SUBMITTED IN SUPPLEMENT XXX

or

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 219083/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISION FOR NDA 219083

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

As soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in Structured Product Labeling (SPL) format using the FDA automated drug registration and listing system (eLIST). Content of the REMS document must be identical to the approved REMS document. The SPL will be publicly available.

Information on submitting REMS in SPL format may be found in the guidance for industry *Providing Regulatory Submission in Electronic Format – Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling*.

For additional information on submitting REMS in SPL format, please email FDAREMSwebsite@fda.hhs.gov.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format—Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[4]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

POST APPROVAL FEEDBACK MEETING

New molecular entities qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could

---

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

[6] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

benefit from improvement. If you would like to have such a meeting with us, call the Regulatory Project Manager for this application.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[7].

If you have any questions, please contact Maryam Changi, Regulatory Project Manager, at maryam.changi@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Hylton V. Joffe, MD, MMSc
Director
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and
Research

ENCLOSURES:
- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Container Labeling
- REMS

[7] https://www.uspnf.com/

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

HYLTON V JOFFE
12/19/2025 12:22:15 PM