



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

16 January 2019

Freedom of Information/
Privacy Act Office (Case # FA-19-007713/FP-19-0010)

Dr. Remington Nevin
MuckRock News
DEPT MR 65309
411A Highland Avenue
Somerville, MA 02144-2516

Dear Dr. Nevin:

Your Freedom of Information Act (FOIA) request for record(s) received 12 December 2019 concerning and related to 60 Degrees Pharmaceuticals or any other intermediate wholesaler or distributor, for supplies of tafenoquine (Arakoda) intended for U.S. military use, from 2013 to the date of process of this request, was referred to U.S. Army Medical Materiel Development Activity (USAMMDA), U.S. Army Medical Research and Materiel Command. The request for records were referred on 18 December 2019. Documents collected will be processed by the Staff Action Officer in the Secretary of the General Staff Office and forward to you in accordance with the Freedom of Information Act, 5 United States Code § 552.

Processed information collected will be forwarded to you as soon as possible. If we are unable to find or process this information to you in accordance with the Freedom of Information Act we will immediately communicate this information to you

I have forwarded a copy of this letter to the offices listed above. Please continue to communicate with the undersigned at 301-619-7118 or usarmy.detrick.medcom-usammc.list.foia-mrmc@mail.mil

Sincerely,

A handwritten signature in black ink, reading "Shalli L. Keller", is positioned above the typed name.

Shalli L. Keller
Freedom of Information/Privacy Act Officer
U.S. Army Medical Research
and Materiel Command



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
HEADQUARTERS, US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
810 SCHREIDER STREET
FORT DETRICK, MARYLAND 21702-5000

Office of the Secretary of the General Staff
FOIA #FA-19-0010

5 March 2019

Dr. Remington Nevin
MuckRock News
DEPT MR 63042
411A Highland Avenue
Somerville, MA 02144-2516

Dear Dr. Nevin:

This is in response to your December 11, 2018 Freedom of Information Act request for documents concerning and related to the USAMMDA or other subordinate activity of USAMRMC, and 60 Degrees Pharmaceuticals or any intermediate wholesaler or distributor, for supplies of Tafenoquine (Arakoda) intended for U.S. Military use, from 2013 to the date of processing of this request. The Arakoda (Tafenoquine) Transition Planning Meeting Agenda and meeting minutes with 60P to discuss tafenoquine commercialization documents are enclosed. In accordance with the Freedom of Information Act, information has been withheld (redacted) based on the following exemptions:

Exemption (b)(4) – Permits the withholding of records related to trade secrets and other confidential business information.

Exemption (b)(5) - Permits the withholding of information under the deliberative process privilege, including pre-decisional documents, draft documents, or information that could be withheld under civil discovery, attorney-client, or attorney-work product privileges. Deliberative information consists of recommendations or opinions on legal, policy or other matters that may or may not go directly to the report's approved findings. Pre-decisional information includes intra-agency or inter-agency communications that are antecedent to the adoption of the agency decision. Exemption 5 protects against the premature disclosure of proposed policies and recommendations before they are finally adopted and protects against public confusion that might result from the disclosure of reasons and rationales that may not ultimately be the grounds for an agency's action.

Exemption (b)(6) - Permits the government to withhold information about individuals when the disclosure would constitute a clearly unwarranted invasion into the personal privacy of a third person. When weighing the public interest in knowing how

the government works against the privacy interests of individual persons we may conclude that the requested record contains data of a personal nature and that no significant public interest will be served in the release of that information. Pursuant to Exemption (b)(6), Personally Identifiable Information (PII), to include names, personnel information, social security numbers, email addresses and telephone numbers have been redacted.

Because your request has been partially denied (redacted), you are advised of your right to appeal this determination to the Secretary of the Army. If you decide to appeal at this time, your appeal must be submitted within 90 days of the date of this notification. In your appeal, you must state the basis for your disagreement with the partial denial and the justification for the release of information associated with your request for this command. Your appeal should be addressed to: CDR U.S. Army Medical Command, Attention: Freedom of Information/Privacy Acts Office (MCPA), 2748 Worth Road, JBSA, Fort Sam Houston, Texas 78234-6021, for forwarding, as appropriate, to the Office of the Secretary of the Army. Please enclose a copy of this response along with your Appeal. To ensure proper processing of any appeal, the letter and the envelope should both bear the notation, "Freedom of Information Act Appeal."

Should you have any questions pertaining to the processing of the document I may be reached at (301)-619-7118 or email shalli.l.keller.civ@mail.mil

Respectfully,

A handwritten signature in black ink, appearing to read "Shalli L. Keller", with a long horizontal flourish extending to the right.

Shalli L. Keller
Staff Action Control Officer
Freedom of Information Act Officer
U.S. Army Medical Research and
Material Command

Enclosure

Arakoda™ (Tafenoquine) Transition Planning Meeting Agenda

(b)(5) 0900-1000 (East Coast Time)

Location: USAMMDA Bldg 1430, (b)(5)

(b)(5)

1. Introductions, Purpose of Working Group

(b)(6)

(b)(6)

(b)(6)

2. Review of Issues

(b)(6)

3. Commercialization Plan

(b)(6)

4. Modification of DOD Guidance for Malaria Prophylaxis

(b)(6)

(b)(6)

5. Inclusion of *Arakoda*™ onto DOD Peacetime Procurement Vehicles and Contingency Contracts

(b)(6)

6. Inclusion of *Arakoda*™ onto DOD Formularies

(b)(6)

7. Final Discussion

(b)(5)

MEETING WITH 60P TO DISCUSS TAFENOQUINE COMMERCIALIZATION**PARTICIPANTS:** (b)(6)

(b)(6)

DISCUSSION:

- Priority Review Designation received for TQ; 6 months for FDA review (completed NLT 8 August 2018)
- (b)(4)
- Timeline:

| | |
|--|---------------|
| FDA approval | 8 August 2018 |
| Tablet validation | (b)(4) |
| Packaging validation | (b)(4) |
| Serialization validation | (b)(4) |
| Validation lots shipped to distributor | (b)(4) |
| Commercial launch | (b)(4) |

- Trade name: (b)(4)
- 100mg tablets
- JPMPG: When are the future quarterly meetings?
- White paper for consultant community?
- Brief at MHSRS (60P brief)
- Who at DoD-HA can guide us as to how to approach them to get the word out?
- (b)(5)
- Can industry reps approach individual MTFs?
- Three (3) validation lots will have (b)(4)
 - **Unit of purchase** is (b)(4)
 - **One Unit of purchase will provide prophylaxis for one service member for 1 month.**
 - **Unit of purchase cost** = (b)(4) (estimate, based on estimated cost of (b)(4) per tablet)
 - Cost of the 3 validation lots is estimated at (b)(4)
 - (b)(6) could we commit to buying this amount to support placebo-controlled studies? Perhaps post-market night vision studies? Tolerability studies?
- Logistics: (b)(4) is the Third Party Logistician (part of (b)(4))
 - They can also do serialization
 - From (b)(4) → Wholesalers (b)(4) etc)
 - (My NOTE: I think (b)(6) reference to wholesalers is the same as what we term as prime vendor distributor)

- Is there a survey that we can generate to gauge potential use?
 - Summary of Potential Actions for USAMMDA:
 - Can the Army commit to buying a certain amount of TQ to support post-marketing studies?
 - Can industry reps approach individual MTFs?
 - (b)(4)
 - Who at DoD-HA can we contact reference TQ?
 - When are future JPMPG quarterly meetings?
 - Can we persuade DoD-HA to recommend TQ for malaria treatment?
 - Can we get TQ into the appropriate unit assemblages? Need to engage the USAMMA pharmacist.
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(b)(5) (on/about)

IMPROMPTU MEETING WITH (b)(6)

SUBJECT: POTENTIAL COURSES OF ACTION TO FUND PROCUREMENT OF TAFENOQUINE

According to (b)(6) some courses of action:

- (b)(5)
- (b)(5)
- (b)(5)