CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-799

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**ODS CONSULT #:** 05-0069
March 10, 2005	June 12, 2005	
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October 13, 2004	August 13, 2005	

TO: Renata Albrecht, M.D.
Director, Division of Special Pathogens and Immunologic Drug Products
HFD-590

THROUGH: Kristen Miller
Project Manager, Division of Special Pathogens and Immunologic Drug Products
HFD-590

PRODUCT NAME:	**NDA SPONSOR:** Mutual Pharmaceutical Co., Inc.
Quinine Sulfate Capsules USP, 324 mg **NDA#:** 21-799	

SAFETY EVALUATOR: Charlie Hoppes, R.Ph., M.P.H.

RECOMMENDATIONS:

1. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review in order to minimize potential errors with the use of this product.

2. DMETS recommends that both new drug reviewing divisions, the Division of Special Pathogens and Immunologic Drug Products and the Division of Cardio-Renal Drug Products, as well as the Office of Generic Drugs, request that application holders of quinine [redacted] revise the principal display panel of container labels to make use of "TALL MAN" differentiation.

3. DMETS recommends that the sponsor provide adequate education regarding the use of quinine to treat malaria upon product launch.

4. DMETS recommends that the sponsor provide adequate education that this product is not indicated for leg cramps upon product launch.

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Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety
HFD-420; PKLN Rm. 6-34
Center for Drug Evaluation and Research

LABEL AND LABELING REVIEW

DATE OF REVIEW: May 20, 2005

NDA# 21-799

NAME OF DRUG: Quinine Sulfate Capsules USP, 324 mg

NDA HOLDER: Mutual Pharmaceutical Co., Inc.

I. INTRODUCTION:

This consult was written in response to a request from the Division of Special Pathogens and Immunologic Drug Products (HFD-590), for assessment of the container labels, insert labeling, and patient information for Quinine Sulfate Capsules USP.

The sponsor has submitted an application for the use of quinine sulfate to treat uncomplicated *Plasmodium falciparum* malaria. Quinine sulfate previously had the approved indications for treatment of malaria as a supplement to other anti-malarial drug products.

Members of DMETS participated in a telecon, dated July 12, 2005, regarding this application. At that time, DMETS summarized review findings regarding medication errors discovered during searches of post-marketing databases. DMETS expressed concern regarding errors involving confusion between quinine and quinidine and errors resulting from off-label use of quinine for leg cramps. DMETS commented that the proposed statements in the INDICATIONS AND USAGE section of package insert labeling regarding what quinine is not indicated for, might better appear in other sections of insert labeling. The Division will further discuss the placement of the "not for" statements currently appearing in the INDICATIONS AND USAGE section of draft insert labeling. The division also explained that labeling statements regarding [redacted] have been removed from the [redacted] section. Additionally, the division stated that the Division of Surveillance, Research, and Communication Support (DSRCS), would be contacted regarding patient information.

PRODUCT INFORMATION

Quinine Sulfate Capsules is indicated for the treatment of uncomplicated *Plasmodium falciparum* malaria. The usual adult dosage for this new indication is 648 mg (two capsules) three times daily for seven days. Quinine Sulfate Capsules will be available in bottles of 30, 100, 500, and 1000 count.

II. SAFETY EVALUATOR RISK ASSESSMENT:

Since quinine has been marketed for many years, DMETS conducted searches of the Adverse Event Reporting System (AERS) and the Drug Quality Reporting System (DQRS) to determine the degree of post-marketing errors with quinine sulfate products. AERS was searched using the terms: MedDRA Preferred Terms (PTs), "Medication Error", "Accidental Overdose", "Overdose", "Pharmaceutical Product Complaint", and "Treatment Non-Compliance", and the drug names, "quinine%", and "quinidine%". The DQRS was also searched for reports of medication errors. This search strategy uncovered 26 errors with quinine products. Two issues emerged following review of these cases (1) established name confusion between quinine and quinidine and (2) concerns with off-label use. The results are discussed below.

A. Established Name Confusion (Quinine/Quinidine, n=22)

DMETS has long been aware of medication errors resulting from confusion between quinine sulfate and quinidine sulfate products. In fact, quinine and quinidine appear on lists of look-alike and sound-alike name pairs, such as that published by U.S. Pharmacist[1]. From searches of AERS and DQRS, DMETS identified 22 medication error cases citing confusion between quinine sulfate and quinidine sulfate or quinidine gluconate (see Appendix A). Of the 22 cases of error between quinine and quinidine, 11 patients received quinidine when quinine was intended, 9 quinine when quinidine was intended, and the remaining two cases were of unspecified confusion between quinine and quinidine. Of the 11 cases of patients inadvertently receiving quinidine when quinine was intended, 6 report the administration of quinidine, one describing patient harm. In the latter report, the patient stated that she was very sleepy, with blurred vision and a rash on the back, shoulders and breast. Of the 9 cases of quinine rather than quinidine, there were 4 cases of patient administration, two cases of which describe harm. It was unclear from one of the reports whether the patient received the incorrect medication. Adverse reactions described in two of the cases include; lack of sleep and ringing in the ears, and syncope, bradycardia, and atrial fibrillation. Two of the 22 reports of confusion between quinine and quinidine described did not indicate whether quinine was confused for quinidine or vice versa. One of the reports cited the potential for name confusion due to similar names and the other reporter described quinine mixed with quinidine in the pharmacy stock.

Upon reviewing AERS cases, DMETS determined that the main root causes of confusion between quinine and quinidine cited by reporters are similar appearance and sound of each name, similar storage location, and computer order entry problems due to the shared first letters of each name, "Quini".

The look-alike and sound-alike similarities between quinine and quinidine stem from shared letters, "quini" to begin each name and the "ine" endings. To further complicate matters, the products are stored in close proximity on pharmacy shelves. The similarity in names is further compounded on computer order entry. The first five letters are identical. Many short codes developed for physician order entry incorporate these first few letters and strength into the short code so that when the short code is entered, a pick list pops up which may result in choosing the wrong item or inputting a similar but different code. The following excerpts

[1] Web Reference: http://www.uspharmacist.com/oldformat.asp?url=newlook/files/Feat/DrugList.htm&pub_id=8&article_id=822

from the medication error reports serve to illustrate the similarities as a source of product confusion.

- Drugs with similar names mixed up (Quinine Sulfate and Quinidine Sulfate).

- ...look alike/sound alike names.

The following excerpts from the medication error reports serve to illustrate proximity of quinine and quinidine on the shelf, as a source of product confusion.

- "...quinine and quinidine are located next to each other and therefore it is easier to select a wrong product."

- "It's too easy to mistake quinine and quinidine due to proximity on shelf....It would be very easy to overlook quinine for quinidine and not note tab vs cap in a busy pharmacy.

The following excerpts from the medication error reports serve to illustrate computer order entry problems as a source of product confusion.

- "...pharmacy computer input error due to similar memonics (sic). Input QUIN 200 rather than the correct QUIND 200...patient received Quinine rather than Quinidine."

- She acknowledged that she did fill this prescription. She stated during the process of typing the prescription information into computer system, she must have picked a wrong one. The technician selected the wrong drug from the self because the inaccurate information imprinted.

To avert incorrect computer entry problems pharmacy practice modifications have been suggested by reporters. Such practice modifications seeking to minimize incorrect selection of quinine/quinidine from a computer pick list are exemplified by the following excerpt:

> Do not have both strengths of each tablet available; for look alike/sound alike names. Do not use "Quin" as phenumonic (sic) for computer. Computer give some signal to make you look twice at what you ordered. Keep Quinine nonformulary (make computer default to nonform. mode).

DMETS acknowledges the need for pharmacy practice modifications to prevent incorrect selection of quinine/quinidine from a computer pick list and publications may be useful. Since FDA has no authority in revising an established name, we recommend differentiation in the names with the use of "Tall Man" lettering described in Section III. of this review. The use of Tall Man Lettering may be useful in preventing selection error and is a tool which may be useful in reducing confusion between quinine and quinidine products. In 2001, the Office of Generic Drugs began a project to differentiate established names of look-alike drug products using "Tall Man Lettering". The project is described in more detail at the following web site: http://www.fda.gov/cder/drug/mederrors/nameDiff.htm

The purpose of using Tall Man Lettering is to make names of drug products look different and to make the healthcare provider aware that there may be another product which looks similar. An Institute of Safe Medication Practices article[2] cites a study done in a controlled setting where the use of Tall Man Lettering decreased errors by 35%. For pharmacies where drug products are stored alphabetically by established name, it would be expected that quinine and quinidine products would be in close proximity. This close proximity might lead to selection error. Use of Tall Man Lettering to distinguish the quinine and quinidine labels, could alert pharmacists to the fact that these names are similar to names of other marketed products.

[2] Medication Safety Alert! For Every Problem a Solution, For Every Solution a Problem. 2004. 9(4), 2.

B. Reports Concerning Off-Label Use of quinine for leg cramps (n=4)

The use of quinine for leg cramps is not an approved indication. However, from searches of AERS and DQRS, DMETS identified 4 reports of confusion or concern regarding the off-label use of quinine for leg cramps (see Appendix A). One concern is that although quinine is widely used to alleviate leg cramps, there is a paucity of patient and prescriber information. This lack of patient information may be attributed to confusion and patient harm as exemplified by the following excerpt:

> Reporter states the directions are misleading. The directions read "take 1 tablet every four hours for malaria." Reporter feels the most common use of Quinine over the counter is for leg cramps and the directions should read take 1-2 tablets per day for leg cramps. The reporter also states the patient experienced some dysuria after taking the Quinine for leg cramps at the dose recommended for malaria.

DMETS acknowledges comments from the division in the telecon dated July 12, 2005, that the "not [redacted] for the treatment of nocturnal leg cramps" statement appearing the INDICATIONS AND USAGE section [redacted]

Overall, the change in the indications and usage of this product poses no safety risk from a medication errors perspective. The dose and dosing interval remains the same. Health care practitioners will need to be educated on the new use of the product in addition to revising the labels and labeling as outlined in Section III. below.

III. LABELING, PACKAGING, AND SAFETY RELATED ISSUES:

In the review of the container labels, insert labeling, and patient information of Quinine Sulfate Capsules USP, DMETS has attempted to focus on safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, which might minimize potential user error.

A. DMETS recommends that the sponsor educate healthcare practitioners that quinine is to be used only for the treatment of uncomplicated malaria and not for leg cramps.

B. CONTAINER LABEL (30's, 100's, 500's, and 1000's)

Following review of the post-marketing errors with quinine, and in order to facilitate the prevention of medication errors resulting from the incorrect selection of quinine sulfate capsules, DMETS recommends that "Tall Man" letters be used to differentiate this product from quinidine sulfate products. Please revise the established name of this product accordingly as follows:

quinINE [redacted]

C. INSERT LABELING

1. TITLE

Revise to correct the name of this product, "Quinine Sulfate Capsules USP, 324 mg".

2. INDICATIONS AND USAGE

D. PATIENT INFORMATION

1. Some terms and phrasing of this patient information may be difficult for patients to comprehend. DMETS acknowledges that the division intends to contact DSRCS regarding the best communication of the patient information for quinine sulfate.

2. Please reprint this information at the end of the professional package insert labeling, as required by 21 CFR 201.57(f)(2).

APPEARS THIS WAY
ON ORIGINAL

IV. RECOMMENDATIONS:

A. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review that might lead to safer use of the product. We would be willing to revisit these issues if the Division receives another draft of the labeling from the manufacturer.

B. DMETS recommends that both new drug reviewing divisions, the Division of Special Pathogens and Immunologic Drug Products and the Division of Cardio-Renal Drug Products, as well as the Office of Generic Drugs, request that application holders of quinin[redacted] .evise the principal display panel of container labels to make use of "TALL MAN" differentiation.

C. DMETS recommends that the sponsor provide adequate education regarding the use of quinine to treat malaria upon product launch.

D. DMETS recommends that the sponsor provide adequate education that this product is not indicated for leg cramps upon product launch.

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, project manager, at 301-827-1998.

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Safety Evaluator
Division of Medication Errors and Technical Support
Office of Drug Safety

Concur:

Alina Mahmud, RPh, MS
Team Leader
Division of Medication Errors and Technical Support
Office of Drug Safety

Appendix A. Selected Medication Error Reports of Confusion Involving Quinine Drug Products (From DQRS and AERS)

AERS# and/or (DQRS #) DATE	TYPE OF ERROR	ABBREVIATED NARRATIVE
		Quinine when Quinidine Intended
4097920-7 (000728) 16-MAY-00	Wrong Drug	A patient was prescribed Quinidine 324 mg by mouth twice a day (to be given at 0900 and 2100) among other medications. In filling the patient's 24-hour drug supply in the pharmacy the evening before delivery, the pharmacist omitted this medication. The medications, before leaving the pharmacy on the day of delivery, are first checked by a pharmacist against the pharmacy's written profile, and then again on the nursing unit, against the Medication Administration Record (MAR). The absence of the Quinidine 324mg tablets was not detected by either of these two processes. Prior to 2100, the other pharmacist on staff was called by a nurse asking which Quinidien should she give, having "two different quinidiens" in her hand. The pharmacist told her that it was the 324mg dose but could not remember the particular brand. The nurse brought both "quinidines" up to the nursing unit. The following morning, the pharmacist entered the pharmacy to find a Quinaglute 324 mg tablet (in the manufacturer's unit-dose packaging) on the counter next to the medication sign-out log for after-hour procurements, with only one dose signed out on the log. Phamracy policy states that nursing will bring up enough medication until the pharmacy opens at 0800. After reviewing the pharmacy profile, the pharmacist realized that the Quinidines had not been delivered the day before and promptly went up to the nursing unit to deliver the 0900 dose. The pharmacist arrived on the unit at 0810, looked at the MAR and noticed that the 0900 Quinidine 324mg dose had already been given. Upon questioning as to what she had administered, the nurse showed the pharmacist the opened unit-dose medication. Pharmacist asked nurse why she gave a 0900 medication at 0800. Her comment was that nursing has an hour "leeway" for all medications. The nurse was informed that the hour "leeway" refers to one-half hour before and/or after a dose is scheduled, not an hour before or an hour after. The nurse, who worked the previous evening, had brought up both the Quinine 325mg capsule and the Quinaglute 324mg tablet. She noticed what the medication was supposed to be and administered the correct dose for 2100. She then wrapped tape around the unit-dose package of the Quinine 325mg capsule, wrote on the, "do not use" or words to that effect.
4610931-5 (040861) 04-APR-94	Wrong Drug	Quinine Sulfate was mistakenly administered for Quinidine Sulfate.
4516062-7 (041790) 21-FEB-96	Wrong Drug	Read order for Quinidine incorrectly or selected wrong medication from list on computer (Quinine) (reporter's error was likely of either type). No "short code" was used. Recommendation from reporter to USPC to prevent recurrence: Do not have both strengths of each tablet available; for look alike/sound alike names. Do not use "Quin" as phenumonic for computer. Computer give some signal to make you look twice at what you ordered. Keep Quinine nonformulary (make computer default to nonform. mode).
4190916-6 (080538) 07-JUN-96	Wrong Drug	A pharmacist erroneously dispensed 120 Quinine 5 gr capsules pursuant to a new written prescription for 120 Quinidine Sulfate 300 mg capsules. The patient's agent discovered the error before administering the wrong medication to the patient. The pharmacist also affixed a label on the prescription vial which incorrectly identified the prescriber.
4612459-5 27-APR-92	Wrong Drug	Pharmacy computer input error due to similar memonics Input QUIN 200 rather than the correct QUIND 200 Pt received Quinine rather than Quinidine
3693048-6 27-AUG-98	Wrong Drug	Early in the afternoon on 8-27-98, the pharmacist on duty misread a prescription for Quinidine Sulfate 324 mg as Quinine Sulfate 324 mg. The pharmacist phoned the doctor's office to verify if Quinine Sulfate 325 mg was acceptable since the pharmacy did not have Quinine Sulfate 324 mg in stock. The pharmacist then dispensed Quinine Sulfate 325 mg. The patient recognized that this medication was different from the

		Quinidine Gluconate 324 mg that he had been taking and returned the medication to the pharmacy. The patient did not ingest the Quinine Sulfate 325 mg and received his correct dose of Quinidine Gluconate.
4107802-X 07-MAY-03	Wrong Drug	Today our Drug Information Service was contacted by a patient reporting a medication error as well as side effect from the error. The patient had been receiving Quinaglute (quinidine) for over 15 years in addition to other medications. On he had his prescription filled. Although the label correctly read quinidine tablets, the contents of the drug gin the bottle appeared different to him. He normally receives white tablets and his time received a capsule. However, he did not question the drug he had received and instead began taking the capsule. Shortly after taking the capsule he began to experience lack of sleep and ringing in his ears. He told his physician who could find no reason for its cause, therefore he continued to take the capsule. However, beginning to think he might not be receiving the correct drug, he went back to the pharmacy (approximately 10 days after initiating the wrong drug) that had filled the prescription. The indicated that he was indeed receiving the wrong drug and replace the quinine with quinidine. He stopped taking the quinine approximately 5 days ago today and his hearing has returned, but he is still experiencing insomnia.
3115206-1 12-AUG-98	Wrong Drug	On 7/23/98, Watson Laboratories informed the company that the wife of an 80 year old male consumer had been taking quinidine for "several years". On 7/21/97, the patient received quinine sulfate 200 mg two capsules three times a day in place of quinidine due to pharmacy dispensing error.
3860249-3 25-JAN-02	Wrong Drug	The reporter states that a patient was admitted to hospital with syncope, bradycardia, and AF. Was on quinidine at home. Developed confusion, lower extremity weakness, and became unable to ambulate on her own. Nurse states that patient may have received quinine instead of the prescribed quinaglute.
Received Quinidine when Quinine Intended		
4161264-5 (U 050190) 27-MAY-97	Wrong Drug	Physician wrote prescription for Quinidine rather than Quinine for benign leg cramps. Patient got prescription filled, then realized error and contacted the office the next day. Recommendation from reporter to USPC to prevent recurrence: Double check prescriptions.
4195215-4 (080284) 12-MAY-95	Wrong Drug	1. Dispensed Quinidine Sulfate 200 mg tablets, instead of Quinine Sulfate 200 mg tablets. 2. Dispensed Quinidine Sulfate 200 mg tablets, instead of Quinine Sulfate 200 mg tablets.
4108925-1 (U 000031) 25-FEB-00	Wrong Drug	Patient was supposed to receive Quinine Sulfate 325 mg as phoned in by her physician, but instead receive Quinidine Gluconate 324 mg. The phoned in prescription was written correctly by one staff pharmacist but interperated and filled incorrectly by the other staff pharmacist. The patient had taken one tablet of the Quinidine Gluconate. She was informed by a nurse the following day that the medication was wrong. The pharmacy was notified and exchanged the medication for Quinine Sulfate.
(040349) 23-SEP-92	Wrong Drug	Patient prescribed Quinine 325 mg as outpatient for leg pains. Admitted to hospital and started on Quinidine Gluconate 324 mg in R/O MI. Chart notes do not indicate outcome of Quinidine treatment. Discharge Rx for Quinidine 325 mg questioned by RPh. MD verbally changed Rx to Quinine 325 mg but failed to indicate change in medical record.
4188294-1 (042053) 19-AUG-96	Wrong Drug	MD wrote an Rx for Quinine Sulfate 300 mg. There is no such strength. The RPh didn't realize that Quinine Sulfate did not come in this strength and pulled Quinidine Sulfate 300 mg off the shelf which was very close to Quinine Sulfate 325 mg and filled Rx with it. Recommendation from reporter to USPC to prevent recurrence: MD's need to know Quinine Sulfate does not come in 300 mg. Another MD did the same thing a few months later but error was caught before dispensing.
(080252) 22-MAR-95	Wrong Drug	Rx written for Quinine Sulfate incorrectly with Quinidine Gluconate. Patient Quinidine for 4 months. Did not suffer any adverse effects. Patient is fileing a lawsuit because of RPh's attitude and behavior not because of error. RPh who discovered the error tried to cover up error by selling the Quinine Sulfate over the counter.
080953 (080953) 06-JAN-98	Wrong Drug	On 4/10/97 prescription was written as Quinine 300 mg, one q 6 hrs for cramps. Apparently the prescription was dispensed as Quinine 260 mg but the label read Quinidine 300 mg. On 6/12/97 the prescription was refilled as Quinidine 300 mg which was incorrect medication. The patient was hospitalized and cardiac catheterization was performed. Then on 7/30/97 the prescription was dispensed as Quinine

		260 mg.
3271036-1 27-MAY-99	Wrong Drug	Pharmacist dispensed quinidine sulfate 300 mg tablet instead of the quinine sulfate 324 mg capsules prescribed.
3734651-4 07-JUN-01	Wrong Drug	Patient received quinidine 200 mg from a mail-order pharmacy instead of quinine 260 mg. The patient had taken the medicine as needed for leg cramps over a few month period. No harm occurred to the patien, however, the patient had chronic heart failure and took also digoxin. This error was discovered when a clinic physician asked me to review the medications that this patient was taking. The patient brought in all of his bottles of medication, and I realized that quinidine was not on his active medication list. The patient confirmed that he had been taking the quinidine for his leg cramps. The clinic's electronic records indicated quinine, and a computer-generated prescription was sent to the mail-order pharmacy.
4085953-6 9-AUG-03	Wrong Drug	There was a phone call from customer on 8/9/02 reporting that the wrong medication was dispensed. Her Rx was written for Quinine however Quinidine was dispensed in error. The patient had taken for 29 days and then She called for the refill. When she arrived to picked up- the pharmacist on duty – she is a pharmacy manager as well informed that she had been given the wrong medication on --- The pharmacist then dispensed the correct medication, the patient was NOT charged for the refill and the money was refunded for the initial prescription She received on ___ According to the patient while she was taking the Quinidine Tablets she was very sleepy, blurred vision and rash on back, shoulders and breast. Her doctor prescribed a Medrol Dose Pak to treat rash and cardiogram was performed – the result which was normal. According to the assigned agent, there was a handwritten on the reverse side of the original prescription. "1st refill caught in error dispensed" Also a 2nd lable was fixed of the original prescription for the refill correctly. On 10/11/02, the agent meet with the pharmacist who dispensed in corrected medication. She acknowledged that she did filled this prescription She stated during the process of typing the prescription information into computer system, she must have picked a wrong one. The technician selected the wrong drug from the self because the inaccurate information imprinted. Also Quinine and Quinidine are located next to each other and therefore it is easier to select a wrong product. It was a very busy evening and shorted of help so the time was limited to offer counseling.
4467072-X 04-OCT-04	Wrong Drug	Pt. took QUININE po as an outpt.; admitted to hospital and prescribing resident M.D. prescribed QUINIDINE as an inpt. and R.Ph. verified order and did not compare it to outpt. profile
Quinine and Quinidine Confusing in General		
4606683-5 (040462) 31-DEC-92	Wrong Drug	Drugs with similar names mixed up (Quinine Sulfate and Quinidine Sulfate).
4197650-7 (M 137947) 03-OCT-03	Wrong Drug	On 9/25/3, I noted Quinine mixed up with Quinidine in my pharmacy. While correcting problem, I noted a 500 bottle of Mutual Pharmaceuticals Quinine 504 caps labelled 324mg. Quinine caps come in 200, 260 & 325mg strengths according to Facts & comparisons, traditionally 5 grain is a common dose which = 325. 324 is not a commonly accepted equivalent to 5 grains. Quinidine product = to Quinaglute (5a tabs) It's too easy to mistake Quinine & Quinidine due to proximity on shelf. The only med I know of with a 324 mg dose is Quinaglute & its generics.
Reports Concerning Off-Label Use of quinine for leg cramps		
(D-115603) 25-JUL-94	Improper Dose	Reporter states the directions are misleading. The directions read "take 1 tablet every four hours for malaria." Reporter feels the most common use of Quinine over the counter is for leg cramps and the directions should read take 1-2 tablets per day for leg cramps. The reporter also states the patient experienced some dysuria after taking the Quinine for leg cramps at the dose recommended for malaria.
(021962) 11-OCT-95	Report Regarding Off-Label use (No Error)	Reporter's cardiologist prescribed Quinine Sulfate once a day for leg cramps. The reporter has had relief from the cramps since taking this medication. The reporter understands the FDA has banned its use. As a personal test, the reporter stopped taking the Quinine Sulfate for five days and the cramps returned. The reporter is sure there are other patients who will suffer as much as he when they can no longer get this medication. It's hard to understand why a long prescribed medication that gives relief would be banned. There are so many potent medications available. The reporter would like to know why a relatively mild drug is removed from the market.

(117160) 08-FEB-95	Report Regarding Off-Label use (No Error)	National Data Corporation compiles a patient counseling information receipt that is printed "To treat night leg cramps or treat/prevent malaria". This data is incorrect. The indication "To treat leg cramps" is not an approved use for this product.
(X 021739) 10-AUG-95	Report Regarding Off-Label use (No Error)	Reporter questions why there is no consultant information regarding over-the-counter sale of Quinine. A flat statement should be made and all practitioners notified. The Federal Register only talks of over-the-counter for leg cramps. It should be totally removed from shelves and market if dangerous.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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