U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

Home > Inspections, Compliance, Enforcement, and Criminal Investigations > Enforcement Actions > Warning Letters

Inspections, Compliance, Enforcement, and Criminal Investigations

Claris Lifesciences Limited

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Silver Spring, MD 20993

Warning Letter

VIA UPS

WL: 320-11-003

November 1, 2010

Mr. Arjun S. Handa
Chief Executive Officer & Managing Director
Claris Lifesciences Limited
Chacharwadi - Vasana
Ahmedabad, Gujurat 382 213
India

Dear Mr. Handa,

The U.S. Food and Drug Administration (FDA or Agency), conducted inspections of Claris Lifesciences Limited, located at Chacharwadi - Vasana, Ahmedabad, India, and Claris Lifesciences, Inc. (a wholly-owned subsidiary of Claris Lifesciences Limited), located at 1445 US Route 130, North Brunswick, New Jersey 08902-3100 (hereinafter collectively referred to as "Claris"). The inspection of Claris Lifesciences Limited (hereinafter referred to as "Claris India"), took place during June 5-16, 2010 (June 2010 inspection). The inspections of Claris Lifesciences, Inc. (hereinafter referred to as "Claris U.S."), took place during July 1-13, 2009 (July 2009 inspection), and January 22 to February 2, 2010 (January/February 2010 inspection).

During our June 2010 inspection of Claris India, FDA investigators identified significant violations of Current Good Manufacturing Practice (CGMP) regulations for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Parts 210 and 211. These violations cause your drug products to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 351(a)(2)(B)], in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMP.

The June 2010 inspection also revealed that Claris failed to submit NDA Field Alert Reports (FARs), to FDA in compliance with section 314.81(b)(1) of FDA's regulations [21 C.F.R. § 314.81(b)(1)(ii)], as required by section 505(k) of the Act [21 U.S.C. § 355(k)]. An applicant is required to submit, within three working days of receipt, information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one or more distributed batches of drug product to meet the specifications established for it in the application.

In addition, based on our review of the labeling for your Sodium Bicarbonate Injection drug product, manufactured by Claris India and distributed by and through Claris U.S., and information collected during the inspections of Claris U.S. in July 2009 and January/February 2010, we conclude that Claris has marketed an unapproved new drug without an approved application. The introduction or delivery for introduction into interstate commerce of the product is a violation of sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)]. The unapproved new drug product is also misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)], and therefore, the introduction or delivery for introduction of the drug into interstate commerce is also a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

We have reviewed responses from Claris dated August 12, 2009, October 7, 13, and 30, 2009, February 24, 2010, and July 3, 2010, but conclude that they lack sufficient corrective actions as discussed below.

CGMP VIOLATIONS

Specific violations observed during the June 2010 inspection conducted at Claris India include, but are not limited, to the following:

1. Your firm has failed to thoroughly investigate the failure of a batch or any of its components to meet its specifications whether or not the batch has already been distributed [21 C.F.R. § 211.192].

a. The complaint investigation discussed in the undated report submitted with Claris India's July 2010 response to the FDA Form 483 and titled, "Complaint Investigation Report Metronidazole Injection USP Ondansetron In 5% Dextrose Injection" (Complaint Investigation Report), is inadequate. It lacks sufficient evaluation of several complaints of intravenous (IV) bag contamination, and does not provide scientific justification and supporting evidence regarding the root cause identified. For example:

1) On April 15, 2010, your firm received a complaint from a U.S. distributor (Sagent Pharmaceuticals) informing you that Metronidazole Injection USP IV bags (lot A090744) were contaminated with a swirling mass, which the complainant identified as the fungus *Cladosporium species*. There is no information in the Complaint Investigation Report to show that Claris initiated an investigation to determine the root cause and extent of the problem until April 26, 2010, when Claris received this contaminated large volume parenteral and examined it.

On May 5, 2010 the same customer (Sagent Pharmaceuticals) reported that another lot of Metronidazole Injection USP bags (A090742) was contaminated with fungi (*Mucor species*).

The Complaint Investigation Report does not adequately address either of this complainant's contamination findings, or the root cause of the problems. For example, your customer's test results confirmed the presence of visual contaminants without discovering any leaks in the intravenous (IV) bags. You have claimed that the uniqueness of your firm's method to detect leaks supersedes the customer's methods. Accordingly, you disregarded their findings regarding the integrity of the IV bag because their test was not performed or supervised by your own laboratory. This does not address the presence of fungi. For instance, the investigation conducted by Sagent involving Metronidazole Injection USP bags (lot A090744) did not detect a leak on the IV bag tested (dye penetration by injection), even though fungi (*Cladosporium species*) were found inside the IV bag.

Furthermore, your firm's conclusions were based solely on the returned bags examined, and do not take into account the overall implications, extent, or root cause of the detected contamination.

In your response to this letter, include your final investigation, assessment, rational and the corrective actions implemented addressing your failure to initiate the complaint investigation promptly. Also, explain if the Dye Ingress method (Container Closure Integrity) is still used to release your IV bags to the market, or if a different method was developed as part of the investigation to detect leakage in the bags.

2) On May 6, 2010, your firm received a complaint from the **(b)(4)** indicating a problem when they opened a case that contained six Metronidazole Injection USP IV bags (lot A090460). The technician from the pharmacy observed that fungi were in the IV bag (as well as inside the overwrap). Claris submitted a Field Alert Report (FAR) on June 3, 2010, however, your Complaint Investigation Report indicates that no leak or contamination was found in the bags received from **(b)(4)**. Please explain this discrepancy in your response to this letter.

3) On May 31, 2010, your customer (Pfizer) reported that Metronidazole Injection USP IV bags (lot A090722) were contaminated with fungi (*Cladosporium species*) and Gram positive bacteria (*Brevibacterium casei*). Pfizer returned 33 unopened Metronidazole Injection USP bags, but your Complaint Investigation Report failed to identify the contaminants that Pfizer visually observed in at least 31 of these bags.

4) Through its investigation your firm identified defective printing stereos, along with packaging, shipping, and handling as the primary root causes of the contamination. The Complaint Investigation Report, however, failed to explain why a defective printing stereo would only have affected IV bags that were returned by your customers, and not other lots produced and released for distribution. Moreover, the Complaint Investigation Report lacks supporting evidence to demonstrate that the packaging, shipping, and handling contributed to the contamination.

In your response to this letter, address those issues, and also explain why these stereos were being used during the manufacturing process and how the suppliers of these defective stereos were qualified, and provide a complete explanation of how and when Claris became aware of the defect(s). In your written response to this letter, provide specific information regarding the requalification of the printing operation, and any formal study conducted to demonstrate the new printing parameters that the response states your firm adopted will prevent recurrence of the problem.

5) Claris India acts as a contract manufacturer for IV bag products marketed by other firms, as well as a distributor of some batches under Claris's own label. Your responsibility as a contract manufacturer is to inform all of your customers of a significant production problem or possible product hazard immediately. In fact, Claris India's Quality Agreements with its customers requires that your firm notify the other party within **(b)(4)** business days of any quality issues related to the product. We note that your firm received worrisome complaints of lost IV bag package integrity and contamination. Yet, the Complaint Investigation Report fails to indicate what steps Claris took to ascertain whether other customers were affected by this issue, or to notify all customers of the potential for significant contamination. Please explain how and when Claris identified and informed all customers affected by your IV bag manufacturing problems. Also include your SOP describing how you keep customers promptly informed of significant occurrences (e.g., complaints, OOS, rejections, major deviations or discrepancies, any potential product hazard), concerning the products you manufacture for them.

6) The Complaint Investigation Report also reflects a number of other shortcomings in the investigation. For example, the Complaint Investigation Report fails, among other things, to:

(a) Identify when the problems that lead to the damaged IV bags and contamination of the product started.

(b) Provide a thorough evaluation and supporting evidence regarding the origin of the contamination that extended to at least eight batches of two products - Metronidazole Injection USP bags and Ondansetron Injection USP in 5% Dextrose Injection bags. The contamination was reported through at least five complaints.

(c) Provide a rationale why other products filled in the same packaging line, with the same bags and printing process, were not affected or contaminated. Similar complaints of contamination extended to batches distributed outside the United States, but the Complaint Investigation Report provides no details of when the complaints were received, or whether an investigation was conducted.

(d) Include an evaluation of the time that elapsed between the manufacturing/filling and printing process of the different batches, and the time the contamination was detected and reported by Claris India. The investigation also lacks details regarding the number of examined lots on hand, tests performed, and the sampling plan used.

(e) Supply an evaluation of the set up process, as well as the number and type of damaged bags generated during the set up. We are concerned with your proposed identification of root causes, because it fails to explain how the sharp edges and stereos only affected the bags that complainants identified, and not any of the bags remaining under your control, or other released batches.

Your firm's response dated July 3, 2010 (July 2010 response), does not provide sufficient information regarding the aforementioned issues. Please include in your response to this letter information regarding each of the issues noted above, and include the nature and origin of contamination or leakage complaints received for lots of the same products that may have been distributed outside of the United States. In addition, please provide a summary of your shipping and handling validation studies under stress conditions.

b. Your investigation into an incident involving IV bag filling rooms and Laminar Air Flow (LAFs) losing positive pressure is inadequate. For example,

During the production of Metronidazole Injection USP bags (lot A000241) the bag filling room and LAFs – intended to provide a constant flow of clean air out of the work area to prevent potentially contaminated air from entering – lost positive pressure. Your July 2010 response indicated that your firm rejected only the bags filled after 9:30 a.m. until the line was stopped, despite the fact that in the same response, your firm indicated that the last acceptable positive pressure was at 9:21 a.m. The deviation report, however, failed to provide an adequate rationale for not rejecting all the bags at risk. Specifically, the July 2010 response indicates that the reason for not rejecting the bags filled after 9:21 a.m., which potentially could have been affected, was because the microbial environmental monitoring results were within acceptable limits. This approach, however, is unacceptable because the loss in pressure may also have affected the accuracy or reliability of the environmental monitoring results; there is, thus, no assurance that all bags filled after 9:21 a.m. were unaffected by the loss of positive pressure, and therefore free of microbial contamination.

Your written procedures related to bag filling and environmental monitoring should be revised. They should ensure that all units of drug products filled between the time the last acceptable differential pressure reading was obtained, and the time the room returns to acceptable conditions, be rejected.

As noted above, we are concerned about the inadequate investigation into the contamination of your IV drug products, process deviation, and the inappropriate documentation practices cited during this inspection. Please provide a corrective action plan that describes your revised procedures, corrective and preventive actions, and controls to ensure product quality.

This plan should include a comprehensive retrospective review of your root cause analysis and the effectiveness of your corrective/preventive actions of the contamination in your drug products, raw material suppliers, equipment adequacy, sterilization cycles, and cleaning and maintenance procedures implemented to ensure that all products produced and released by your quality unit meet specifications. It should also include an evaluation of the independence, authority, and effectiveness of your firm's quality unit to rapidly address significant manufacturing issues. A robust quality unit will be essential for your firm to address any emerging or ongoing manufacturing issue in the future, and prevent the distribution of adulterated product.

2. Your firm does not have adequate written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess [21 C.F.R. § 211.100(a)]. For example:

The inspection revealed that your firm fails to have a procedure or process in place to evaluate in-process units that are rejected due to defects during the filling of Metronidazole Injection USP bags. In fact, the investigators documented that for Metronidazole Injection USP bags (lot A000247), 48 rejections occurred during the filling process No deviation was documented and no investigation was conducted, and you have not documented whether or not the rejected units were caused by a significant process deviation that directly affects the integrity of the other IV bags in the production lot.

Your July 2010 response is inadequate because it fails to include your rationale for releasing production lots with unexplained deviations, on the basis that the filling yield was found within limits.

Please provide a retrospective analysis of the in-process and finished units of Metronidazole Injection USP bags, Ciprofloxin Injection USP bags, and Ondansetron Injection USP bags that were rejected due to defects found during your filling, printing, and packaging operations. Include the amount of defective units in this analysis. We also recommend that an adequate timeframe be considered for this study to enable you to establish trends regarding the amount and type of defect, and amount of rejected units per batch. Provide information on the type of defects identified, and the corrective and preventive actions implemented.

3. Your firm failed to assure that equipment used in the manufacture, processing, packing, or holding of a drug product is of appropriate design for its intended use [21 C.F.R. § 211.63]. For example:

The calibration of thermocouples (TCs) used during the validation of your terminal steam sterilizers is not performed before or after the autoclave cycles. Your response failed to provide data to support that the TCs used during the validation runs are within acceptable calibration range. The calibration of these TCs provides assurance of an accurate reading of the temperature in the sterilizer. Please provide your sterilization cycle summary for all the terminal sterilizers and cycles used by your facility, with the appropriate parameters and conclusion of the data generated.

4. Your firm has not established appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile [21 C.F.R. § 211.113(b)]. For example:

The written procedures related to the production simulations – "media fills" - conducted to validate your capability to aseptically produce small volume parenteral (SVP) were found to be inadequate. The media fills for this line did not represent actual operations used in the aseptic production of ampoules and vials. For instance, the media fill performed by your firm in October 2009 failed to simulate the interventions performed in actual, routine production. For example, a routine production of a **(b)(4)** Injection vials lot would take approximately **(b)(4)** hours to be filled. Your written procedures (reflected in production protocols and batch record forms) for routine production require that an intervention take place every **(b)(4)** minutes for fill-weight verification measurements. Our review found, however, written procedures for the media fill simulation (reflected in media fill protocol), require performance of this fill-weight verification measurement only **(b)(4)** times throughout the media fill process. In your response to this letter, provide the finalized protocol and the summary report including all data generated during the execution of this media fill.

5. Your firm does not clean and maintain equipment at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product [21 C.F.R. § 211.67(a)].

During the inspection the investigators observed three dispensing vessels used in the step prior to terminal sterilization that were labeled clean, however, the vessels had liquid residue inside. Your response indicated that this liquid is from final cleaning with **(b)(4)** rinse. The presence of liquid residue in a vessel (labeled as clean) that is later used to manufacture sterile drug products is unacceptable. In your response to this letter, provide the production lot numbers that included use of these vessels. Additionally, provide documentation to support that your firm's cleaning procedures and practices are adequate to prevent contamination of your products. Lastly, provide the investigation report with your findings including the cleaning methods performed, as well as the corrective and preventive actions for all of your other equipment.

6. Batch production and control records prepared for each batch of drug product produced do not include complete information relating to the production and control of each batch [21 C.F.R. § 211.188]. For example:

Your firm failed to exercise adequate control over issuance of production batch records. The inspection revealed that not all pages of the batch record used in the production area are stamped and dated when issued. The purpose of this requirement is to ensure that the correct master production record is used to produce the batch record. There should be procedures and controls in place to maintain the batch record during the manufacturing of your drug product. In your response, provide your established procedures regarding issuance of batch records to provide assurance that appropriate controls are implemented, and that all the accurate pages of the issued batch records and other records are used.

FIELD ALERT REPORTING VIOLATIONS

FDA "Field Alert" reporting requirements require applicants to submit certain information about distributed drug products, including information concerning bacteriological contamination, any significant chemical, physical, or other change or deterioration product, or any failure of a distributed batch to meet the specifications established for it, to the appropriate FDA district office within three working days of receipt by the applicant [21 C.F.R. § 314.81(b)(1)]. The regulation helps establish an "early warning system" by requiring that applicants bring significant problems to the Agency's attention promptly in order to prevent potential safety hazards from drug products already in distribution and also to prevent potential safety hazards with drug products manufactured in the future.

Based on the observations and information obtained during the inspection, Claris failed to submit Field Alert reports as required by 21 C.F.R. § 314.81(b)(1)(ii). For example:

a. Your firm received visibly contaminated Metronidazole Injection USP bags (lot A090744) on April 15, 2010. The field alert report submitted to FDA was dated May 6, 2010.

b. Your firm received a contaminated sample of Metronidazole Injection USP bags (lot A090460) on May 6, 2010, but the field alert report was sent to FDA on June 3, 2010.

c. Your customer (**(b)(4)**) found three instances of a leaking bag with possible microbial growth of Metronidazole Injection Solution Bag and reported this to Claris India on May 20, 2009 (lot A080758), November 10, 2009 (lot A080784), and May 4, 2010 (lot A080765). None of these complaints were sent to FDA.

UNAPPROVED NEW DRUGS VIOLATIONS

Observations and information obtained during the July 2009 and January/February 2010 inspections, and review of labeling, further indicate that Claris, including by and through its wholly-owned subsidiary Claris U.S., has marketed an unapproved new drug in violation of the Act. Specifically, information obtained during those inspections indicates your firm has marketed the following prescription drug:

- Sodium Bicarbonate Injection (8.4% w/v; 250 mL and 500 mL glass vials)

As labeled, the above product is a drug within the meaning of section 201(g)(1)(B) and (C) of the Act [21 U.S.C. § 321(g)(1)(B) and (C)], because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and it is intended to affect the structure of function of the body. Further, this drug product, as marketed by your firm, is a "new drug" within the meaning of section 201(p) of the Act [21 U.S.C. § 321 (p)], because it is not generally recognized as safe and effective for its labeled uses. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331 (d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)], is in effect for the product. Based upon our information, there is no FDA-approved application on file for the above product. The marketing of this product without an approved application constitutes a violation of these provisions of the Act.

Additionally, because the above product is intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for it so that a layman can use this product safely for its intended uses. Consequently, its labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(f)(l) of the Act [21 U.S.C. § 352(f) (1)]. Because your product lacks a required approved application, it is not exempt under 21 C.F.R. § 201.115 from the requirements of section 502 (f)(1) of the Act. The introduction or delivery for introduction into interstate commerce of this product therefore also violates sections 301(a) of the Act [21 U.S.C. § 331(a)].

We acknowledge Claris's assertions of "grandfather" status and have responded to that claim in a letter to Arun Menon, President-North America, Claris U.S., dated May 27, 2010. In summary, materials submitted did not demonstrate that Claris's sodium bicarbonate injection, USP 8.4% as marketed today has the same formulation, strength, dosage form, route of administration, indication, intended patient populations, and other conditions of use as a pre-1938 product.

There was no evidence indicating your product is identical to a product, bearing labeling containing identical representations concerning the conditions of its use, that was introduced prior enactment of the Act in 1938.

The introduction or delivery for introduction into interstate commerce of misbranded products without approved new drug applications violates, inter alia, sections 301(a) and 301(d) of the Act [21 U.S.C. §§ 331(a), 331(d)]. Therefore, Claris should discontinue distributing this unapproved new drug immediately. In addition, new drugs without an approved application as required may not be lawfully imported into the United States. Therefore, new drugs without an approved application are subject to refusal of admission pursuant to section 801(a)(3) of the Act [21 U.S.C. § 381 (a)(3)].

We request that you outline the action Claris is taking to discontinue the marketing of this unapproved new drug product. Also please note that if you are no longer marketing this product, you must update the drug listing files in accordance with 21 C.F.R. § 207.30(a)(2).

ADVERSE DRUG EXPERIENCE REPORTS

Section 505(k)(1) of the Act [21 U.S.C. § 355(k)(1)], and 21 C.F.R. §§ 314.80 and 314.98***1***, require an applicant to establish and maintain records and make reports to FDA of adverse drug experiences, along with certain other data or information. Failure to comply with section 505(k) of the Act is a prohibited act under section 301(e) of the Act [21 U.S.C. § 331(e)]. In addition, section 310.305 of FDA's regulations, [21 C.F.R. § 310.305], requires manufacturers, packers, and distributors who market prescription drug products that are not the subject of approved drug applications, to establish and maintain records and make reports to FDA of serious, unexpected adverse drug experiences associated with the use of their drug products.

During our July 2009 and January/February 2010 inspections of Claris U.S., FDA investigators identified violations of post-marketing adverse drug experience reporting regulations of Title 21, Code of Federal Regulations Parts 310 and 314, and section 505(k)(1) of the Act [21 U.S.C. § 355(k) (1)]. We acknowledge the responses, dated August 12, 2009, October 7, 13, and 30, 2009, and February 24, 2010, from Arun Menon, President of Claris U.S., to the FDA Form 483s issued following the inspections, and Claris's stated commitment to developing and implementing adequate written procedures, including a number of promised additions and changes to Claris India procedures (SOPs) for handling ADE reporting. Indeed, information obtained from the inspections and the Claris responses also indicates that Claris India and Claris U.S. have shared responsibility for activities involved in meeting their ADE reporting obligations under FDA regulations. Claris also indicated certain activities have been transferred to an independent contractor, **(b)(4)**. We note, however, that Claris has not provided all of the SOPs noted in its correspondence and, hence, the revised procedures for certain ADE reporting activities remain unclear. We request that Claris meet with FDA staff to discuss a resolution to this situation.

CONCLUSION

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence and the occurrence of other violations. If you wish to ship your products to and distribute them in the United States, it is the responsibility of your firm to ensure compliance with all U.S. standards for CGMP and all applicable U.S. laws and regulations.

You should take prompt action to correct the violations cited in this letter. Until all corrections have been completed and FDA has confirmed corrections of the violations and your firm's compliance with CGMP, FDA may withhold approval of any new applications or supplements listing your firm as a drug product manufacturer. In addition, until such time as your manufacturing practices are verified to comply with CGMPs, your firm will remain under FDA Import Alert, and FDA will continue to refuse admission of all articles manufactured at Claris India, Chacharwadi - Vasana, Ahmedabad, India into the United States. The articles are subject to refusal of admission pursuant to section 801(a)(3) of the Act [21 U.S.C. § 381 (a)(3)], in that, the methods and controls used in their manufacture do not appear to conform to Current Good Manufacturing Practice within the meaning of section 501(a)(2)(B) of the Act [21 U.S.C. § 351(a)(2)(B)]. Failure to promptly correct violations affecting your products that are being marketed within United States commerce may also result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations and copies of supporting documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the date by which you will have completed the correction.

Additionally, your response should state if you no longer manufacture or distribute Ciprofloxacin, Metronidazole, Ondansetron, Fluconazole, Levofloxacin, **(b)(4)**, and provide the dates and reasons you ceased production. Please identify your response with FEI # 3004610460.

We also recommend that you contact Paul Balcer at Paul.Balcer@fda.hhs.gov, or 301-796-3525, within five days of receipt of this letter to schedule a regulatory meeting with Claris U.S. and Claris India. If you have questions or concerns regarding this letter, contact Maan Abduldayem, Compliance Officer, at the below address and telephone number.

U.S. Food and Drug Administration
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Division of Manufacturing and Product Quality
International Compliance Branch
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Sincerely,
/S/
Deborah M. Autor
Director
Office of Compliance
Center for Drug Evaluation and Research

cc: A Menon, President – North America, Claris Lifesciences, Inc.

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1 Section 314.98 of the regulations requires applicants holding an approved abbreviated new drug application (ANDA) to comply with certain reporting and recordkeeping requirements of 21 CFR § 314.80.

Links on this page: