FLUAD QUADRIVALENT (Influenza Vaccine, Adjuvanted)
Injectable Emulsion for Intramuscular Use
2021-2022 Formula
Initial U.S. Approval: 2020

INDICATIONS AND USAGE

FLUAD QUADRIVALENT is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUAD QUADRIVALENT is approved for use in persons 65 years of age and older. (1)

This indication is approved under accelerated approval based on the immune response elicited by FLUAD QUADRIVALENT (1). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

DOSAGE AND ADMINISTRATION

A single 0.5 mL dose for intramuscular injection. (2.1)

DOSAGE FORMS AND STRENGTHS

Injectable emulsion supplied in 0.5 mL single-dose pre-filled syringes. (3)

CONTRAINDICATIONS

Severe allergic reaction to any component of the vaccine, including egg protein, or after a previous dose of any influenza vaccine. (4, 11)

WARNINGS AND PRECAUTIONS

If Guillain-Barré Syndrome (GBS) has occurred within six weeks of previous influenza vaccination, the decision to give FLUAD QUADRIVALENT should be based on careful consideration of the potential benefits and risks. (5.1)

ADVERSE REACTIONS

The most common (≥ 10%) local and systemic reactions in elderly subjects 65 years of age and older were injection site pain (16.3%), headache (10.8%) and fatigue (10.5%). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 07/2021

FULL PRESCRIBING INFORMATION: CONTENTS

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
   2.1 Dosage and Schedule
   2.2 Administration
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
   5.1 Guillain-Barré Syndrome
   5.2 Preventing and Managing Allergic Reactions
   5.3 Altered Immune Competence
   5.4 Syncope
   5.5 Limitations of Vaccine Effectiveness
6 ADVERSE REACTIONS
   6.1 Clinical Trials Experience
   6.2 Postmarketing Experience
7 DRUG INTERACTIONS
   7.1 Concomitant Use With Other Vaccines
   7.2 Concurrent Use With Immunosuppressive Therapies
8 USE IN SPECIFIC POPULATIONS
   8.1 Pregnancy
   8.2 Lactation
   8.4 Pediatric Use
   8.5 Geriatric Use
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
   12.1 Mechanism of Action
13 NONCLINICAL TOXICOLOGY
   13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
   14.1 Immunogenicity of FLUAD QUADRIVALENT
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.
FULL PRESCRIBING INFORMATION
1 INDICATIONS AND USAGE
FLUAD QUADRIVALENT is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and types B contained in the vaccine. FLUAD QUADRIVALENT is approved for use in persons 65 years of age and older. This indication is approved under accelerated approval based on the immune response elicited by FLUAD QUADRIVALENT [see Clinical Studies (14.1)]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

2 DOSAGE AND ADMINISTRATION
For intramuscular injection only

2.1 Dosage and Schedule
Administer FLUAD QUADRIVALENT as a single 0.5 mL intramuscular injection in adults 65 years of age and older.

2.2 Administration
• Gently shake each syringe. FLUAD QUADRIVALENT has a milky-white appearance. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit [see Description (11)]. If either condition exists, FLUAD QUADRIVALENT should not be administered.
• To use a pre-filled syringe fitted with a Luer Lok system, remove the tip cap by unscrewing it in a counter-clockwise direction. Once the tip cap is removed, attach a needle to the syringe by screwing it on in a clockwise direction until it locks. Once the needle is locked in place, remove the needle protector and administer the vaccine.
• The vaccine should be administered by intramuscular injection, preferably in the region of the deltoid muscle of the upper arm. Do not inject the vaccine in the gluteal region or areas where there may be a major nerve trunk.

3 DOSAGE FORMS AND STRENGTHS
FLUAD QUADRIVALENT is a sterile injectable emulsion supplied in 0.5 mL single-dose pre-filled syringes.

4 CONTRAINDICATIONS
Do not administer FLUAD QUADRIVALENT to anyone with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine, including egg protein [see Description (11)], or to a previous influenza vaccine.

5 WARNINGS AND PRECAUTIONS
5.1 Guillian-Barré Syndrome
If Guillian-Barré syndrome (GBS) has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUAD QUADRIVALENT should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an elevated risk of GBS. [see References (1)] Evidence for a causal relationship of GBS with other influenza vaccines is inconclusive; if an excess risk exists, it is probably slightly more than 1 additional case per 1 million persons vaccinated.

5.2 Preventing and Managing Allergic Reactions
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Altered Immunocompetence
The immune response to FLUAD QUADRIVALENT in immunocompromised persons, including individuals receiving immunosuppressive therapy, may be lower than in immunocompetent individuals. [see Concurrent Use With Immunosuppressive Therapies (7.2)]

5.4 Syncope
Syncope (fainting) may occur in association with administration of injectable vaccines including FLUAD QUADRIVALENT. Ensure procedures are in place to avoid injury from falling associated with syncope.

5.5 Limitations of Vaccine Effectiveness
Vaccination with FLUAD QUADRIVALENT may not protect all vaccine recipients against influenza disease.

6 ADVERSE REACTIONS
The most common (≥10%) local and systemic reactions in elderly subjects 65 years of age and older were injection site pain (16.3%), headache (10.8%) and fatigue (10.5%).

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, the adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect rates observed in clinical practice.

The safety of FLUAD QUADRIVALENT was evaluated in two clinical studies in 4269 elderly subjects 65 years of age and older. Study 1 (NCT02587221) was a multi-center, randomized, observer-blind, non-influenza comparator-controlled efficacy and safety study conducted in 12 countries during the 2016-2017 Northern Hemisphere and 2017 Southern Hemisphere seasons. In this study, 3381 subjects received FLUAD QUADRIVALENT and 3380 subjects received a US-licensed non-influenza comparator vaccine (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Boostrix® [GlycoSmithKline Biologicals]). The mean age of subjects at enrollment was 72 years, 62% were female, 48% White, 34% Asian, 16% Other, 2% American Indian/Alaska Native, and 18% of Hispanic/Latino ethnicity.

Solicited local and systemic adverse reactions were collected for 7 days after vaccination in a subset of 665 subjects who received FLUAD QUADRIVALENT and 667 subjects who received the comparator vaccine. The percentages of subjects reporting solicited local adverse reactions are presented in Table 1a and systemic adverse reactions are presented in Table 1b. Onset usually occurred within the first 2 days after vaccination. The majority of solicited reactions resolved within 3 days.

Table 1a. Percentages of Subjects Reporting Solicited Local Adverse Reactions in the Solicited Safety Population within 7 Days of Vaccination (Study 1)

<table>
<thead>
<tr>
<th>Local (Injection site) Reactions</th>
<th>FLUAD QUADRIVALENT N=595-659</th>
<th>Non-Influenza Comparator Vaccine N=607-664</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injection site pain</td>
<td>16.3%</td>
<td>11.2%</td>
</tr>
<tr>
<td>Erythema ≥25mm</td>
<td>3.8%</td>
<td>1.8%</td>
</tr>
<tr>
<td>Induration ≥25mm</td>
<td>4.0%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Ecchymosis ≥25mm</td>
<td>0.5%</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

Study 1: NCT02587221
Abbreviation: N=number of subjects with solicited safety data
Non-Influenza Comparator Vaccine = combined Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Boostrix® (GlycoSmithKline Biologicals)
All solicited local adverse events reported within 7 days of vaccination are included
Solicited Safety Population: all subjects in the exposed population who received a study vaccine and provided post-vaccination solicited safety data
Serious reactions of each type were reported in 1.1% or fewer subjects receiving FLUAD QUADRIVALENT; severe reactions of each type were also reported in the comparator group at similar percentages. Severe definitions: Erythema, Induration and Ecchymosis > 25 mm diameter; Injection site pain, = prevents daily activity.

Table 1b. Percentages of Subjects Reporting Solicited Systemic Adverse Reactions in the Solicited Safety Population within 7 Days of Vaccination (Study 1)

<table>
<thead>
<tr>
<th>Systemic Reactions</th>
<th>FLUAD QUADRIVALENT N=595-659</th>
<th>Non-Influenza Comparator Vaccine N=607-664</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>10.8%</td>
<td>8.3%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>10.5%</td>
<td>8.8%</td>
</tr>
<tr>
<td>Myalgia</td>
<td>7.7%</td>
<td>6.1%</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>7.3%</td>
<td>6.6%</td>
</tr>
<tr>
<td>Chills</td>
<td>5.0%</td>
<td>3.9%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4.1%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Nausea</td>
<td>3.8%</td>
<td>2.3%</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>3.6%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Fever ≥100.4°F (38°C)</td>
<td>1.7%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.8%</td>
<td>1.1%</td>
</tr>
</tbody>
</table>

Study 1: NCT02587221
Abbreviation: N=number of subjects with solicited safety data
Non-Influenza Comparator Vaccine = combined Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Boostrix® (GlycoSmithKline Biologicals)
All solicited systemic adverse events reported within 7 days of vaccination are included
Solicited Safety Population: all subjects in the exposed population who received a study vaccine and provided post-vaccination solicited safety data
Serious reactions of each type were reported in 1.1% or fewer subjects receiving FLUAD QUADRIVALENT; severe reactions of each type were also reported in the comparator group at similar percentages. Severe definitions: Nausea, Fatigue, Myalgia, Arthralgia, Headache, and Chills = prevents daily activity; Loss of appetite = not eating at all; Vomiting = 6 or more times in 24 hours or requires intravenous hydration; Diarrhea = 6 or more loose stools in 24 hours or requires intravenous hydration; Fever > 102.2°F (39°C).

Unsolicited adverse events (AEs) were collected for all subjects for 21 days after vaccination. Related unsolicited AEs were reported by 303 (9.0%) and by 261 (7.7%) of the subjects for FLUAD QUADRIVALENT and Boostrix, respectively. For FLUAD QUADRIVALENT, injection site pain and influenza-like illness were the only unsolicited adverse reactions reported in ≥ 1% of subjects (1.7% and 1.5%, respectively). Serious adverse events (SAEs) and potentially immune-mediated adverse events of special interest (AESIs) were collected up to 366 days after vaccination. SAEs were reported by 238 (7.0%) FLUAD QUADRIVALENT recipients and 234 (6.9%) comparator recipients. There were no SAEs, AESIs or deaths in this study that were related to FLUAD QUADRIVALENT.

Study 2 (NCT03314662) was a multicenter, randomized, double-blind, comparator-controlled study conducted during the 2017-18 Northern Hemisphere influenza season. In this study, 888 subjects received FLUAD QUADRIVALENT, 444 subjects received the licensed RO spiritual..
adjuvanted trivalent vaccine (aTIV-1 - FLUAD® (trivalent formulation)) and 444 subjects received an adjuvanted trivalent influenza vaccine with an alternate B strain (aTIV-2).

The mean age of subjects at enrollment who received FLUAD QUADRIVALENT was 72.5 years. Female subjects represented 56.6% of the study population and the racial distribution of subjects was 91.6% Caucasian, 7.0% Black or African American, and ≤ 1% each for Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native or Other.

Solicited local and systemic adverse reactions were reported within 7 days after vaccination were similar to those reported for Study 1. Un solicited AEs were collected for 21 days after vaccination. Related unsolicited AEs were reported by 39 (4.4%) and by 17-19 (3.8%–4.3%) of subjects administered FLUAD QUADRIVALENT or aTIV, respectively. For FLUAD QUADRIVALENT, injection site bruising (1.0%) was the only unsolicited adverse reaction reported in ≥ 1% of subjects.

Serious AEs and AEsIs were collected up to 181 days after vaccination. Within 6 months after vaccination, 37 (4.2%) FLUAD QUADRIVALENT recipients and 18-28 (4.1%–6.3%) aTIV recipients experienced an SAE. There were no SAEs, AEsIs or deaths in this study that were related to the study vaccine. There were no AEs leading to withdrawal from the study.

6.2. Postmarketing Experience

There are no postmarketing data available for FLUAD QUADRIVALENT. However, the postmarketing experience with FLUAD (trivalent formulation) is relevant to FLUAD QUADRIVALENT because both vaccines are manufactured using the same process and have overlapping compositions. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Blood and lymphatic system disorders:

Thrombocytopenia (some cases were severe with platelet counts less than 5,000 per mm³), lymphadenopathy

General disorders and administration site conditions:

Extensive swelling of injected limb lasting more than one week, injection site cellulitis-like reactions (some cases of swelling, pain, and redness extending more than 10 cm and lasting more than 1 week)

Immune system disorders:

Allergic reactions including anaphylactic shock, anaphylaxis, and angioedema

Musculoskeletal and connective tissue disorders:

Muscular weakness

Nervous system disorders:

Encephalomyelitis, Guillain-Barré Syndrome, convulsions, neuritis, neuralgia, parasthesia, syncope, presyncope

Skin and subcutaneous tissue disorders:

Generalized skin reactions including erythema multiforme, urticaria, pruritus or non-specific rash

Vascular disorders:

Vasculitis, renal vasculitis

7 DRUG INTERACTIONS

7.1. Concomitant Use With Other Vaccines

No clinical data on concomitant administration of FLUAD QUADRIVALENT with other vaccines is available.

If FLUAD QUADRIVALENT is given at the same time as other injectable vaccine(s), the vaccine(s) should be administered at different injection sites.

Do not mix FLUAD QUADRIVALENT with any other vaccine in the same syringe.

7.2. Concurrent Use With Immunosuppressive Therapies

Immunosuppressive or corticosteroid therapies may reduce the immune response to FLUAD QUADRIVALENT.

8 USE IN SPECIFIC POPULATIONS

8.1. Pregnancy

Risk Summary

FLUAD QUADRIVALENT is not approved for use in persons < 65 years of age. There are insufficient human data to establish whether there is a vaccine-associated risk with use of FLUAD QUADRIVALENT in pregnancy.

There were no developmental toxicity studies of FLUAD QUADRIVALENT performed in animals. A developmental toxicity study has been performed in female rabbits administered FLUAD (trivalent formulation) prior to mating and during gestation. A 0.5 mL dose was injected on each occasion (a single human dose is 0.5 mL). (see 8.1 Animal Data).

Animal Data

In a developmental toxicity study, the effect of FLUAD (trivalent formulation) was evaluated in pregnant rabbits. Animals were administered FLUAD (trivalent formulation) by intramuscular injection twice prior to gestation, during the period of organogenesis (gestation day 7) and later in pregnancy (gestation day 20). 0.5 mL (45 mcg) perrabbit/occasion. No vaccine-related fetal malformations or variations and no adverse effects on pre-weaning development were observed in the study.

8.2. Lactation

FLUAD QUADRIVALENT is not approved for use in persons < 65 years of age. No human or animal data are available to assess the effects of FLUAD QUADRIVALENT on the breastfeeding infant or on milk production/excretion.

8.4. Pediatric Use

Safety and effectiveness of FLUAD and FLUAD QUADRIVALENT (same manufacturing process and overlapping composition with FLUAD) were evaluated in clinical trials conducted in children 6 months to <72 months of age. Data from these trials are inconclusive to demonstrate the safety and effectiveness of FLUAD QUADRIVALENT in children 6 months to <72 months of age. The safety and effectiveness of FLUAD QUADRIVALENT in infants less than 6 months of age and in children older than 72 months of age have not been evaluated.

8.5. Geriatric Use

Safety and immunogenicity of FLUAD QUADRIVALENT have been evaluated in adults 65 years of age and older. [See Adverse Reactions (6.1) and Clinical Studies (14)]
13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

FLUAD QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. FLUAD (trivalent formulation) did not affect female fertility in a rabbit developmental toxicity study [see Pregnancy (8.1)].

14 CLINICAL STUDIES

14.1 Immunogenicity of FLUAD QUADRIVALENT

Immunogenicity of FLUAD QUADRIVALENT was evaluated in Study 1 (NCT02587221), a randomized, observer-blind, non-influenza comparator-controlled multicenter efficacy study conducted in 12 countries during the 2016-2017 Northern Hemisphere and 2017 Southern Hemisphere seasons. In this study, elderly subjects 65 years of age and older received one dose of either FLUAD QUADRIVALENT (N=3379) or a US-licensed non-influenza comparator vaccine (Boostrix; N=3382). Immunogenicity was evaluated 21 days after vaccination in a subgroup of subjects in a 4:1 ratio: FLUAD QUADRIVALENT (N=1324) and non-influenza control vaccines (N=332). In the immunogenicity set, the mean age across both vaccination groups was 72 years and females represented 59% of subjects. The racial distribution of subjects consisted of 89% Caucasian, 11% Asian and <1% American Indian or Alaska Native.

Immunogenicity endpoints measured 3 weeks after vaccination included percentage of subjects with HI titer ≥1:40 and percentage of subjects who achieved seroconversion. Success criteria required the lower bound of the 2-sided 95% CI for the proportion of subjects with an HI titer ≥1:40 to be ≥60% and for the lower bound of the 2-sided 95% CI for the proportion of subjects with seroconversion to be ≥30%. Antibody responses for all 4 strains are presented in Table 2.

Immunogenicity endpoints measured 3 weeks after vaccination included percentage of subjects with HI titer ≥1:40 and percentage of subjects who achieved seroconversion. Success criteria required the lower bound of the 2-sided 95% CI for the proportion of subjects with an HI titer ≥1:40 to be ≥60% and for the lower bound of the 2-sided 95% CI for the proportion of subjects with seroconversion to be ≥30%. Antibody responses for all 4 strains are presented in Table 2.

Table 2: Immune Responses 21 Days After Vaccination with FLUAD QUADRIVALENT or a Non-Influenza Comparator Vaccine in Elderly Subjects 65 years of Age and Older (Study 1)

<table>
<thead>
<tr>
<th>Strain</th>
<th>Prop. of subjects with HI titer ≥1:40 (95% CI)</th>
<th>Prop. of subjects with HI titer ≥1:40 (95% CI)</th>
<th>Seroconversionb (95% CI) FLUAD QUADRIVALENT</th>
<th>Seroconversionb (95% CI) Non-Influenza Comparator Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>A/H1N1</td>
<td>96.2% (95.1%, 97.2%)</td>
<td>46.7% (41.2%, 52.2%)</td>
<td>78.0% (75.7%, 80.2%)</td>
<td>2.1% (0.9%, 4.3%)</td>
</tr>
<tr>
<td>A/H3N2</td>
<td>95.6% (94.4%, 96.7%)</td>
<td>41.7% (36.3%, 47.2%)</td>
<td>84.6% (82.5%, 86.5%)</td>
<td>3.9% (2.1%, 6.6%)</td>
</tr>
<tr>
<td>B/Yamagata</td>
<td>79.2% (77.0%, 81.4%)</td>
<td>21.5% (17.2%, 26.4%)</td>
<td>60.8% (58.1%, 63.4%)</td>
<td>3.6% (1.9%, 6.3%)</td>
</tr>
<tr>
<td>B/Victoria</td>
<td>81.6% (79.4%, 83.7%)</td>
<td>18.4% (14.4%, 23.0%)</td>
<td>65.5% (62.9%, 68.1%)</td>
<td>2.1% (0.9%, 4.3%)</td>
</tr>
</tbody>
</table>

Abbreviations: CI=Confidence Interval, N=number of subjects in full analysis immunogenicity set.

Non-Influenza Comparator Vaccine = combined Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Boostrix® (GlaxoSmithKline Biologicals).  
Seroconversion is defined as a pre-vaccination HI titer <1:10 and post-vaccination HI titer ≥ 1:40 or at least a 4-fold increase in HI from pre-vaccination HI titer ≥ 1:10. Success criteria: the LB of the 95% CI for the SCR must be ≥30%.

15 REFERENCES


16 HOW SUPPLIED/STORAGE AND HANDLING

FLUAD QUADRIVALENT is supplied in the product presentation listed below:

<table>
<thead>
<tr>
<th>Presentation</th>
<th>NDC Number</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Filled Syringe</td>
<td>70461-121-03</td>
<td>0.5 mL dose in a pre-filled syringe (needle not supplied), package of 10 syringes per carton [NDC 70461-121-04]</td>
</tr>
</tbody>
</table>

Store FLUAD QUADRIVALENT refrigerated at 2°C to 8°C (36°F to 46°F). Protect from light. Do not freeze. Discard if the vaccine has been frozen. Do not use after expiration date.

The syringe, syringe plunger stopper and tip cap are not made with natural rubber latex.

17 PATIENT COUNSELING INFORMATION

• Inform vaccine recipients of the potential benefits and risks of immunization with FLUAD QUADRIVALENT.
• Educate vaccine recipients regarding the potential side effects. Clinicians should emphasize that (1) FLUAD QUADRIVALENT contains non-infectious particles and cannot cause influenza and (2) FLUAD QUADRIVALENT is intended to help provide protection against illness due to influenza viruses only.
• Instruct vaccine recipients to report adverse reactions to their healthcare provider and/or to Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov. Provide vaccine recipients with the Vaccine Information Statements which are required by the National Childhood Vaccine Injury Act of 1986. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).
• Inform vaccine recipients that annual vaccination is recommended.

FLUAD QUADRIVALENT is a registered trademark of Seqirus UK Limited or its affiliates. MF59® is a trademark of Novartis AG.

Manufactured by:
Seqirus Inc., 475 Green Oaks Parkway, Holly Springs, NC 27540, USA

Distributed by:
Seqirus USA Inc., 25 Deforest Avenue, Summit, NJ 07901, USA
Tel: 1-855-358-8966
US License No. 2049