Important Safety Information (cont’d)

If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA should be based on careful consideration of the potential benefits and risks.

If AFLURIA is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

AFLURIA should be given to a pregnant woman only if clearly needed.

AFLURIA has not been evaluated in nursing mothers. It is not known whether AFLURIA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA is administered to a nursing woman.

Antibody responses in persons 65 years of age and older were lower after administration of AFLURIA as compared to younger adult subjects.

In children 5 through 17 years of age, most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were pain, redness, and swelling. The most common systemic adverse events were headache, myalgia, irritability, malaise, and fever.

In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were tenderness, pain, swelling, and redness. The most common systemic adverse reactions observed were muscle aches, headache, and malaise.

In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies with AFLURIA when administered by the PharmaJet® Stratis® Needle-Free Injection System up to 7 days post-vaccination were tenderness, swelling, pain, redness, itching, and bruising. The most common systemic adverse events within this period were myalgia, malaise, and headache.

In adults 65 years of age and older, the most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were tenderness and pain.

Vaccination with AFLURIA may not protect all individuals.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit http://www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see accompanying full prescribing information for AFLURIA.

AFLURIA offers the following product benefits:

- Experienced manufacturer with year-round seasonal production for both the Northern and Southern hemispheres
- Projected prebook delivery completion by end of September 2015®
- Strong historical track record of timely & consistent delivery performance

AFLURIA®, influenza vaccine, is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. Administration of AFLURIA with a needle and syringe is approved for use in persons 5 years of age and older. Administration of AFLURIA with the PharmaJet® Stratis® Needle-Free Injection System is approved for use in persons 18 through 64 years of age only.

AFLURIA is contraindicated in individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine.

Administration of CSL's 2010 Southern Hemisphere influenza vaccine was associated with postmarketing reports of increased rates of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years; these increased rates were confirmed by postmarketing studies. Febrile events were also observed in children 5 to less than 9 years of age.

Please see additional Important Safety Information on reverse side and full prescribing information provided by your sales representative.
AFLURIA offers the following product benefits:

- Experienced manufacturer with year-round seasonal production for both the Northern and Southern hemispheres
- Delivery estimated to begin August 2015*
- Projected prebook delivery completion by end of September 2015*
- Strong historical track record of timely & consistent delivery performance

HELP YOUR PATIENTS
STAND STRONG AGAINST THE FLU WITH AFLURIA

Available in 2 presentations:
- Single-Dose, Pre-Filled Luer-Lok™ Syringes (preservative-free)
- 10-Dose Multi-Dose Vials

AFLURIA offers the following product benefits:

- Cost-effective TIV flu vaccine option
- Not made with natural rubber latex
- Peel-off labels for patient claim coding
- Preservative-free pre-filled syringe option

Important Safety Information (cont’d)

If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA should be based on careful consideration of the potential benefits and risks.

If AFLURIA is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

AFLURIA should be given to a pregnant woman only if clearly needed.

AFLURIA has not been evaluated in nursing mothers. It is not known whether AFLURIA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA is administered to a nursing woman.

Antibody responses in persons 65 years of age and older were lower after administration of AFLURIA as compared to younger adult subjects.

In children 5 through 17 years of age, most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were pain, redness, and swelling. The most common systemic adverse events were headache, myalgia, irritability, malaise, and fever.

In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were tenderness, pain, swelling, and redness, itching. The most common systemic adverse reactions observed were muscle aches, headache and malaise.

In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies with AFLURIA when administered by the PharmaJet Stratis Needle-Free Injection System up to 7 days post-vaccination were tenderness, swelling, pain, redness, itching and bruising. The most common systemic adverse events within this period were myalgia, malaise, and headache.

In adults 65 years of age and older, the most common injection-site adverse reactions observed in clinical studies of AFLURIA when administered by needle and syringe were tenderness and pain. Vaccination with AFLURIA may not protect all individuals.

Widely recognized manufacturer with year-round seasonal production for both the Northern and Southern hemispheres

Delivery estimated to begin August 2015*

*Pending CBER release.

**Projected prebook delivery completion by end of September 2015**

Strong historical track record of timely & consistent delivery performance

Important Safety Information

Please see additional Important Safety Information on reverse side and full prescribing information provided by your sales representative.

AFLURIA*, influenza vaccine, is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. Administration of AFLURIA with a needle and syringe is approved for use in persons 5 years of age and older. Administration of AFLURIA with the PharmaJet Stratis® Needle-Free Injection System is approved for use in persons 18 through 64 years of age only.

AFLURIA is contraindicated in individuals with known severe allergic reactions (eg, anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine.

Administration of CSL’s 2010 Southern Hemisphere influenza vaccine was associated with postmarketing reports of increased rates of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years; these increased rates were confirmed by postmarketing studies. Febrile events were also observed in children 5 to less than 9 years of age.

Please see accompanying full prescribing information for AFLURIA.
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AFLURIA safely and effectively. See full prescribing information for AFLURIA.

AFLURIA, Influenza Vaccine
Suspension for Intramuscular Injection
2014-2015 Formula
Initial U.S. Approval: 2007

RECENT MAJOR CHANGES
Dosage and Administration (2) 08/2014

INDICATIONS AND USAGE
- AFLURIA is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. (1)
- AFLURIA is approved for use in persons 5 years of age and older. (1)

DOSE FORMS AND STRENGTHS
For intramuscular (IM) injection only, by needle and syringe (5 years of age and older) or by PharmaJet® Stratis® Needle-Free Injection System (18 through 64 years of age). A single dose is 0.5 mL (2)

<table>
<thead>
<tr>
<th>Age</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 years through 8</td>
<td>One dose or two doses at least 1 month apart*</td>
</tr>
<tr>
<td>9 years and older</td>
<td>One dose</td>
</tr>
</tbody>
</table>

*1 or 2 doses depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines. (2.1)

CONTRAINDICATIONS
- Severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine. (4, 11)

WARNINGS AND PRECAUTIONS
- Administration of CSL’s 2010 Southern Hemisphere influenza vaccine was associated with increased rates of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years. Febrile events were also observed in children 5 through 8 years of age. (5.1)

ADVERSE REACTIONS
- In children 5 through 17 years of age, the most common injection-site adverse reactions when administered by needle and syringe were pain (≥60%), redness (≥20%) and swelling (≥10%). The most common systemic adverse events were headache, myalgia (≥20%), irritability, malaise and fever (≥10%). (6.1)
- In adults 18 through 64 years of age, the most common injection-site adverse reactions when administered by needle and syringe were tenderness (≥60%), pain (≥40%), swelling (≥20%), and redness, itching (≥10%). The most common systemic adverse events were muscle aches (≥30%) and headache, malaise (≥20%). (6.1)
- In adults 65 years of age and older, when administered by needle and syringe the most common injection-site adverse reactions were tenderness (≥30%) and pain (≥10%). No systemic adverse events occurred in ≥10% of subjects in this age group. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact bioCSL Inc. at 1-844-275-2461 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

ADVERSE REACTIONS
- Safety and effectiveness of AFLURIA have not been established in pregnant women or nursing mothers. (8.1, 8.3)
- Antibody responses were lower in geriatric subjects than in younger subjects. (8.5)
- AFLURIA is not approved for use in children less than 5 years of age because of increased rates of fever and febrile seizures. One comparator-controlled trial demonstrated higher rates of fever in recipients of AFLURIA as compared to a trivalent inactivated influenza vaccine control. (8.4)

See 17 for PATIENT COUNSELING INFORMATION. Revised: 08/2014

FULL PRESCRIBING INFORMATION: CONTENTS*

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
  5.1 Fever and Febrile Seizures
  5.2 Guillain-Barré Syndrome
  5.3 Preventing and Managing Allergic Reactions
  5.4 Altered Immunocompetence
  5.5 Limitations of Vaccine Effectiveness
6 ADVERSE REACTIONS
  6.1 Clinical Trials Experience
  6.2 Postmarketing Experience
  6.3 Adverse Reactions Associated With Influenza Vaccination
7 DRUG INTERACTIONS
  7.1 Concurrent Use With Other Vaccines
  7.2 Concurrent Use With Immunosuppressive Therapies
8 USE IN SPECIFIC POPULATIONS
  8.1 Pregnancy
  8.3 Nursing Mothers
  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 Efficacy Against Laboratory-Confirmed Influenza
  14.2 Immunogenicity in Children—Administration via Needle and Syringe
  14.3 Immunogenicity in Adults and Older Adults—Administration via Needle and Syringe
  14.4 Immunogenicity in Adults—Administration via PharmaJet Stratis Needle-Free Injection System
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
  16.1 How Supplied
  16.2 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
AFLURIA is an inactivated influenza vaccine indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. AFLURIA is approved for use in persons 5 years of age and older.

2 DOSAGE AND ADMINISTRATION
For intramuscular (IM) injection only, by needle and syringe (5 years of age and older) or by PharmaJet® Stratis® Needle-Free Injection System (18 through 64 years of age). A single dose is 0.5 mL. The dose and schedule for AFLURIA are presented in Table 1.

Table 1: AFLURIA Schedule

<table>
<thead>
<tr>
<th>Age</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 years through 8 years</td>
<td>One dose or two doses at least 1 month apart *</td>
</tr>
<tr>
<td>9 years and older</td>
<td>One dose</td>
</tr>
</tbody>
</table>

*1 or 2 doses depends on vaccination history as per Advisory Committee on Immunization Practices annual recommendations on prevention and control of influenza with vaccines.

Shake thoroughly and inspect visually before use. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever suspension and container permit. If either of these conditions exists, the vaccine should not be administered.

May be administered by needle and syringe (5 years of age and older) or PharmaJet Stratis Needle-Free Injection System (18 through 64 years of age only). When using the single-dose pre-filled syringe, shake the syringe thoroughly and administer the dose immediately. When using the multi-dose vial, shake the vial thoroughly before withdrawing each dose, and administer the dose immediately.

- **N**eedle and **S**yringe: Draw up the exact dose using a separate sterile needle and syringe for each individual patient. It is recommended that small syringes (0.5 mL or 1 mL) be used to minimize any product loss.
- **P**harmaJet Stratis Needle-Free Injection System: For instructions on withdrawal of a 0.5 mL dose and use of the PharmaJet Stratis Needle-Free Injection System, refer to the Instructions For Use for the PharmaJet Stratis Needle-Free Injection System.

The preferred site for intramuscular injection is the deltoid muscle of the upper arm. Between uses, return the multi-dose vial to the recommended storage conditions between 2-8°C (36-46°F). **Do not freeze.** Discard if the vaccine has been frozen.

3 DOSAGE FORMS AND STRENGTHS
AFLURIA is a sterile suspension for intramuscular injection (see Description [11]). AFLURIA is supplied in two presentations:
- 0.5 mL pre-filled syringe (single dose).
- 5 mL multi-dose vial (ten 0.5 mL doses).

4 CONTRAINDICATIONS
AFLURIA is contraindicated in individuals with known severe allergic reactions (e.g., anaphylaxis) to any component of the vaccine including egg protein, or to a previous dose of any influenza vaccine (see Description [11]).

5 WARNINGS AND PRECAUTIONS

5.1 FEVER AND FEBRILE SEIZURES
Administration of CSL’s 2010 Southern Hemisphere influenza vaccine was associated with postmarketing reports of increased rates of fever and febrile seizures in children predominantly below the age of 5 years as compared to previous years; these increased rates were confirmed by postmarketing studies. Febrile events were also observed in children 5 through 8 years of age.

5.2 GUILLAIN-BARRÉ SYNDROME
If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA should be based on careful consideration of the potential benefits and risks. The 1976 swine influenza vaccine was associated with an increased frequency of GBS. Evidence for a causal relation of GBS with subsequent vaccines prepared from other influenza viruses is unclear. If influenza vaccine does pose a risk, it is probably slightly more than one additional case per 1 million persons vaccinated.

5.3 PREVENTING AND MANAGING ALLERGIC REACTIONS
Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.4 ALTERED IMMUNOCOMPETENCE
If AFLURIA is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

5.5 LIMITATIONS OF VACCINE EFFECTIVENESS
Vaccination with AFLURIA may not protect all individuals.

6 ADVERSE REACTIONS
In children 5 through 17 years of age, the most common injection-site reactions observed in clinical studies with AFLURIA administered by needle and syringe were pain (≥60%), redness (≥20%) and swelling (≥10%). The most common systemic adverse events were headache, myalgia (≥20%), irritability, malaise and fever (≥10%).

In adults 18 through 64 years of age, the most common injection-site adverse reactions observed in clinical studies with AFLURIA administered by needle and syringe were tenderness (≥60%), pain (≥40%), swelling (≥20%), redness and itching (≥10%). The most common systemic adverse events observed were muscle aches (≥30%), headache and malaise (≥20%).

In adults 18 through 64 years of age, using the PharmaJet Stratis Needle-Free Injection System, the most common injection-site adverse reactions observed in a clinical study with AFLURIA up to 7 days post-vaccination were tenderness (≥80%), swelling, pain, redness (≥60%), itching (≥20%) and bruising (≥10%). The most common systemic adverse events within this period were myalgia, malaise (≥30%) and headache (≥20%).

In adults 65 years of age and older, the most common injection-site adverse reactions observed in clinical studies with AFLURIA administered by needle and syringe were tenderness (≥30%) and pain (≥10%). No systemic adverse reactions occurred in ≥10% of subjects in this age group.

6.1 CLINICAL TRIALS EXPERIENCE
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a vaccine cannot be directly compared to rates in the clinical studies of another vaccine and may not reflect the rates observed in clinical practice.

Children
In clinical studies, AFLURIA has been administered to, and safety information collected for, 3,009 children ages 6 months through 17 years. Clinical safety data for AFLURIA in children are presented from three clinical studies (Studies 1, 2 and 3). Data from a comparator-controlled trial (Study 1) are presented, followed by pooled data from two open label studies (Studies 2 and 3). Subjects 6 months through 8 years of age received one or two vaccinations, administered by needle and syringe, as determined by previous vaccination history (for further details on clinical study design, dosing and demographics see Clinical Studies [14]).

Study 1 included 1,468 subjects for safety analysis, ages 6 months through 17 years, randomized to receive AFLURIA (735 subjects) or another U.S.-licensed trivalent inactivated influenza vaccine (manufactured by Sanofi Pasteur, Inc.) (733 subjects).

Study 2 included 1,976 subjects for safety analysis, ages 6 months through 17 years. All subjects received AFLURIA.

Study 3 included 298 subjects for safety analysis, ages 6 months through 8 years. All subjects received AFLURIA.

The safety assessment was similar for the three pediatric studies. Local (injection site) adverse reactions and systemic adverse events were solicited for 7 days post-vaccination (Tables 2 and 3). Unsolicited adverse events were collected for 30 days post-vaccination. All adverse events are presented regardless of any treatment causality assigned by study investigators. Among the pediatric studies, there were no vaccine-related deaths or vaccine-related serious adverse events reported in children 5 years of age and older. In this section, safety data from the pediatric studies are limited to children 5 years of age and older. AFLURIA is not approved for use in children less than 5 years of age. See Warnings and Precautions [5.1] and Use in Specific Populations [8.4] for risks of AFLURIA in children less than 5 years of age.

In the comparator-controlled trial (Study 1), the rate of fever after the first dose of AFLURIA in subjects aged 5 through 8 years was 16% as compared to 8% in subjects who received the comparator. The rate of fever in subjects aged 9 through 17 years following a single dose of AFLURIA was 6% as compared to 4% in subjects who received the comparator. In all three pediatric studies, the rates of fever in subjects aged 5 through 8 years who received AFLURIA were lower after dose 2 than dose 1.

Data in Tables 2 and 3 are presented for children 5 years and older.
Table 2: Proportion of Subjects 5 through 17 Years of Age with Solicited Local Adverse Reactions or Systemic Adverse Events within 7 Days after Administration of First or Second Dose of AFLURIA, Irrespective of Causality (Study 1)

<table>
<thead>
<tr>
<th>Percentage* of Subjects in each Age Group Reporting Event</th>
<th>Subjects 5 through 8 years</th>
<th>Subjects 9 through 17 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFLURIA N=161(^b)</td>
<td>Comparator N=165(^b)</td>
<td>AFLURIA N=254(^b)</td>
</tr>
<tr>
<td><strong>After the First Dose</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>63</td>
<td>60</td>
</tr>
<tr>
<td>Redness</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td>Induration</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td><strong>Systemic Adverse Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>34</td>
<td>30</td>
</tr>
<tr>
<td>Malaise</td>
<td>24</td>
<td>13</td>
</tr>
<tr>
<td>Headache</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Any Fever</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>Fever ≥102.2°F</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Nausea/ Vomiting</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td><strong>AFLURIA N=39</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>After the Second Dose</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Adverse Reactions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>36</td>
<td>38</td>
</tr>
<tr>
<td>Redness</td>
<td>10</td>
<td>19</td>
</tr>
<tr>
<td>Induration</td>
<td>8</td>
<td>17</td>
</tr>
<tr>
<td>Systemic Adverse Events</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>Headache</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Myalgia</td>
<td>13</td>
<td>17</td>
</tr>
<tr>
<td>Malaise</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Nausea/ Vomiting</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Any Fever</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Fever ≥102.2°F</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Proportion of subjects reporting each solicited local adverse reaction or systemic adverse event by treatment group based on the number of subjects contributing at least one data value for an individual sign/symptom (individual event denominators).

Adul ts

In clinical studies comparing AFLURIA to placebo or another U.S.-licensed trivalent inactivated influenza vaccine, a single dose of AFLURIA was administered to, and safety information collected for, 11,104 subjects ages 18 through 64 years and 836 subjects ages 65 years and older. Clinical safety data for AFLURIA in adults are presented from three clinical studies (Studies 4 through 6). In these studies, AFLURIA and comparator vaccine or placebo were administered by needle and syringe.

Study 4 included 1,357 subjects for safety analysis, ages 18 through 64 years, randomized to receive AFLURIA (1,089 subjects) or placebo (268 subjects) (see Clinical Studies [14]).

Study 5 included 15,020 subjects for safety analysis, ages 18 through 64 years, randomized to receive AFLURIA (10,015 subjects) or placebo (5,005 subjects) (see Clinical Studies [14]).

Study 6 included 1,266 subjects for safety analysis, ages 65 years and older, randomized to receive AFLURIA (630 subjects) or another U.S.-licensed trivalent inactivated influenza vaccine manufactured by Sanofi Pasteur Inc. as an active comparator (636 subjects) (see Clinical Studies [14]). The safety assessment was identical for the three adult studies. Local (injection-site) adverse reactions and systemic adverse events were solicited for 5 days post-vaccination (Table 4). Unsolicited adverse events were collected for 21 days post-vaccination. All adverse events are presented regardless of any treatment causality assigned by study investigators. Among adult studies 4 through 6, there were no vaccine-related deaths or vaccine-related serious adverse events reported.

Table 3: Proportion of Subjects 5 through 17 Years of Age with Solicited Local Adverse Reactions or Systemic Adverse Events Within 7 Days after Administration of AFLURIA, Irrespective of Causality (Studies 2 and 3)

<table>
<thead>
<tr>
<th>Percentage* of Subjects in each Age Group Reporting Event</th>
<th>Subjects 2 and 3</th>
<th>Subjects 18 through 64 years</th>
<th>Subjects ≥ 65 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFLURIA N=1087-1088(^b)</td>
<td>Placebo N=266(^b)</td>
<td>AFLURIA N=10,015(^b)</td>
<td>Placebo N=5,005(^b)</td>
</tr>
<tr>
<td>AFLURIA N=630(^b)</td>
<td>Comparator N=636(^b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenderness (Pain on touching)</td>
<td>60</td>
<td>18</td>
<td>69</td>
</tr>
<tr>
<td>Pain (without touching)</td>
<td>40</td>
<td>9</td>
<td>48</td>
</tr>
<tr>
<td>Redness</td>
<td>16</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Swelling</td>
<td>9</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Bruising</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Systemic Adverse Events</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>26</td>
<td>26</td>
<td>25</td>
</tr>
<tr>
<td>Malaise</td>
<td>19</td>
<td>19</td>
<td>29</td>
</tr>
<tr>
<td>Muscle aches</td>
<td>13</td>
<td>9</td>
<td>21</td>
</tr>
<tr>
<td>Nausea</td>
<td>6</td>
<td>9</td>
<td>7</td>
</tr>
<tr>
<td>Chills/ Shivering</td>
<td>3</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Fever</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>

*Proportion of subjects reporting each solicited local adverse reaction or systemic adverse event by treatment group based on the number of subjects contributing at least one data value for an individual sign/symptom (individual event denominators).

\(N\) = number of subjects in the Safety Population for each treatment group.

* These preferred terms were used to describe Solicited Adverse Events in Study 2.

* These preferred terms were used to describe Solicited Adverse Events in Study 3.
In Study 4, headache was the only unsolicited adverse event that occurred in ≥ 5% of subjects who received AFLURIA or placebo (8% versus 6%, respectively). In Study 5, headache was the only unsolicited adverse event that occurred in ≥ 5% of subjects who received AFLURIA or placebo (12% versus 11%, respectively). Studies 1 to 6 were all conducted when AFLURIA was administered by needle and syringe.

Additionally, safety information has been collected in a clinical study of AFLURIA administered using the PharmaJet Stratis Needle-Free Injection System (Study 7). Study 7 included 1,247 subjects for safety analysis, ages 18 through 64 years, randomized to receive AFLURIA by either the PharmaJet Stratis Needle-Free Injection System (624 subjects) or needle and syringe (623 subjects). No deaths or vaccine-related serious adverse events were reported in Study 7. Local (injection-site) adverse reactions and systemic adverse events were solicited for 7 days post-vaccination (Table 5).

Table 5: Proportion of Subjects 18 through 64 Years of Age with Solicited Local Adverse Reactions or Systemic Adverse Events within 7 Days after Administration of AFLURIA by PharmaJet Stratis Needle-Free Injection System or Needle and Syringe irrespective of causality (Study 7).

<table>
<thead>
<tr>
<th>Symptom</th>
<th>AFLURIA N=540-616</th>
<th>Needle and Syringe N=599-606</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Local Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tenderness</td>
<td>89</td>
<td>78</td>
</tr>
<tr>
<td>Swelling</td>
<td>65</td>
<td>20</td>
</tr>
<tr>
<td>Pain</td>
<td>64</td>
<td>49</td>
</tr>
<tr>
<td>Redness</td>
<td>60</td>
<td>19</td>
</tr>
<tr>
<td>Itching</td>
<td>28</td>
<td>10</td>
</tr>
<tr>
<td>Bruising</td>
<td>18</td>
<td>5</td>
</tr>
<tr>
<td><strong>Systemic Adverse Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td>36</td>
<td>36</td>
</tr>
<tr>
<td>Malaise</td>
<td>31</td>
<td>28</td>
</tr>
<tr>
<td>Headache</td>
<td>25</td>
<td>22</td>
</tr>
<tr>
<td>Chills</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Nausea</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Fever</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Proportion of subjects reporting each local adverse reaction or systemic adverse event by treatment group based on the number of subjects contributing at least one data value for an individual sign/symptom (individual event denominators).

Microscopic polyangiitis (vasculitis) has been reported temporally associated with influenza vaccination. 7. DRUG INTERACTIONS

7.1 CONCURRENT USE WITH OTHER VACCINES

There are no data to assess the concomitant administration of AFLURIA with other vaccines. AFLURIA is given at the same time as another injectable vaccine(s), the vaccine(s) should be administered in separate syringes and a separate arm should be used.

AFLURIA should not be mixed with any other vaccine in the same syringe or vial.

7.2 CONCURRENT USE WITH IMMUNOSUPPRESSIVE THERAPIES

The immunological response to AFLURIA may be diminished in individuals receiving corticosteroid or immunosuppressive therapies.

8 USE IN SPECIFIC POPULATIONS

8.1 PREGNANCY

Pregnancy Category B: A reproductive and developmental toxicity study has been performed in female rats at a dose approximately 265 times the human dose (on a mg/kg basis) and revealed no evidence of impaired female fertility or harm to the fetus due to AFLURIA. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, AFLURIA should be given only if clearly needed.

In the reproductive and developmental toxicity study, the effect of AFLURIA on embryo-fetal and pre-weaning development was evaluated in pregnant rats. Animals were administered AFLURIA by intramuscular injection twice prior to gestation, once during the period of organogenesis (gestation day 6), and once later in pregnancy (gestation day 20). 0.5 mL/rat/occasion (approximately a 265-fold excess relative to the projected human dose on a body weight basis).

No adverse effects on mating, female fertility, pregnancy, parturition, lactation parameters, and embryo-fetal or pre-weaning development were observed. There were no vaccine-related fetal malformations or other evidence of teratogenesis.

8.3 NURSING MOTHERS

AFLURIA has not been evaluated in nursing mothers. It is not known whether AFLURIA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA is administered to a nursing woman.

8.4 PEDIATRIC USE

AFLURIA is not approved for use in children less than 5 years of age. In a clinical study in which children received AFLURIA or a US-licensed comparator vaccine (Study 1, see Clinical Trials Experience, 8.1), the incidence of fever in children 6 months through 35 months of age following the first and second doses of AFLURIA were 37% and 15%, respectively, as compared to 14% following each dose in the comparator group. Among children 3 years through 4 years of age, the incidence of fever following the first and second doses of AFLURIA were 32% and 14%, respectively, as compared to 11% and 16% in the comparator. In an open-label study (Study 2), fever, irritability, loss of appetite, and vomiting/diarrhea occurred more frequently in children 6 months through 35 months of age as compared to older children. Across three pediatric studies of AFLURIA (Studies 1, 2, and 3), 1.2% of eligible children (n=1,764) were discontinued from the second vaccination because of severe fever (≥ 104°F) within 48 hours of the first vaccination. Across the three pediatric studies, two children, a 7-month old and a 3-year old, experienced vaccine-related febrile seizures (rate of 0.07% across studies), one of which was serious.

Administration of CSL’s 2010 Southern Hemisphere influenza vaccine was 7-month old and a 3-year old, experienced vaccine-related febrile seizures (rate of 0.07% across studies), one of which was serious.

8.5 EFFECTS ON FERTILITY

The available data are insufficient to assess the effects of AFLURIA on fertility in either males or females. AFLURIA’s effects on male fertility have not been evaluated in animal reproduction studies.

8.6 PREGNANCY

In a study in which microparticulate gold particles were injected intramuscularly in pregnant rabbits, an increase in the number of resorptions and a decrease in implantation rates were observed in the offspring of females treated with a dose (on a body weight basis) approximately 300 times the human dose. Studies in rabbits have suggested that a testis-specific factor is produced following vaccination with AFLURIA; however, this has not been confirmed in human studies. The relationship of these observations to the human condition is unknown.

8.7 Lactation

AFLURIA is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA is administered to a nursing woman.

8.8 EFFECTS ON CHILDREN

AFLURIA is not approved for use in children less than 5 years of age.
14.1 EFFICACY AGAINST LABORATORY-CONFIRMED INFLUENZA

In Study 5, the efficacy of AFLURIA was demonstrated in a randomized, observer-blind, placebo-controlled study conducted in 15,044 subjects. Healthy subjects 18 through 64 years of age were randomized in a 2:1 ratio to receive a single dose of AFLURIA (enrolled subjects: 10,033; evaluable subjects: 9,889) or placebo (enrolled subjects: 5,011; evaluable subjects: 4,960). The mean age of all randomized subjects was 35.5 years. 54.4% were female and 90.2% were White. Laboratory-confirmed influenza was assessed by active and passive surveillance of influenza-like illness (ILI) beginning 2 weeks post-vaccination until the end of the influenza season, approximately 6 months post-vaccination. ILI was defined as at least one respiratory symptom (e.g., cough, sore throat, nasal congestion) and at least one systemic symptom (e.g., oral temperature of 100.0°F or higher, feverishness, chills, body aches). Nasal and throat swabs were collected from subjects who presented with an ILI for laboratory confirmation by viral culture and real-time reverse transcription polymerase chain reaction. Influenza virus strain was further characterized using gene sequencing and phylogenetic analysis.

Attack rates and vaccine efficacy, defined as the relative reduction in the influenza infection rate for AFLURIA compared to placebo, were calculated using the per protocol population. Vaccine efficacy against laboratory-confirmed influenza infection due to influenza A or B virus strains contained in the vaccine was 60% with a lower limit of the 95% CI of 41% (Table 6).

### Table 6: Laboratory-Confirmed Influenza Infection Rate and Vaccine Efficacy in Adults 18 through 64 Years of Age (Study 5)

<table>
<thead>
<tr>
<th>Vaccine-matched Strains</th>
<th>Subjects</th>
<th>Laboratory-Confirmed Influenza Cases</th>
<th>Influenza Infection Rate</th>
<th>Vaccine Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFLURIA</td>
<td>9,889</td>
<td>58</td>
<td>0.59</td>
<td>60</td>
</tr>
<tr>
<td>Placebo</td>
<td>4,960</td>
<td>73</td>
<td>1.47</td>
<td>41</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any Influenza Virus Strain</th>
<th>Subjects</th>
<th>Laboratory-Confirmed Influenza Cases</th>
<th>Influenza Infection Rate</th>
<th>Vaccine Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFLURIA</td>
<td>222</td>
<td>22</td>
<td>2.24</td>
<td>42</td>
</tr>
<tr>
<td>Placebo</td>
<td>192</td>
<td>38</td>
<td>1.87</td>
<td>28</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval

* The Per Protocol Population was identical to the Evaluable Population in this study.

** Vaccine efficacy = 1 minus the ratio of AFLURIA/placebo infection rates. The objective of the study was to demonstrate that the lower limit of the CI for vaccine efficacy was greater than 40%.

14.2 IMMUNOGENICITY IN CHILDREN—ADMINISTRATION VIA NEEDLE AND SYRINGE

Study 1 was a randomized, observer-blind, comparator-controlled study to evaluate the immunological non-inferiority of AFLURIA to a U.S.-licensed trivalent inactivated influenza vaccine (manufactured by Sanofi Pasteur, Inc.) in subjects 6 months through 17 years of age. Study vaccines were administered by needle and syringe. Results are presented for children 5 through 17 years of age (Table 7). A total of 832 subjects (aged 5 through 17 years) were enrolled. Subjects were randomized in a 1:1 ratio to receive AFLURIA (enrolled subjects: 417; evaluable subjects: 383) or the comparator vaccine (enrolled subjects: 415; evaluable subjects: 383). Children 6 months through 8 years of age with no history of influenza vaccination received 2 doses approximately 28 days apart. Children 6 months through 8 years of age with a history of influenza vaccination and children 9 years of age and older received 1 dose. Children 6 months through 35 months of age received 0.25 mL of AFLURIA or comparator influenza vaccine, and children 3 years of age and older received 0.5 mL of AFLURIA or comparator influenza vaccine. Nearly equal proportions of subjects were male (49.0%) and female (50.1%), and the majority were White (85.0%) or Black (10.3%). Immunogenicity assessments were performed prior to vaccination and at 21 days after vaccination. The co-primary endpoints were HI Geometric Mean Titer (GMT) ratios (adjusted for baseline HI titer) and the difference in seroconversion rates for each vaccine strain 21 days after the final vaccination.

Pre-specified non-inferiority criteria required that the upper bound of the 2-sided 95% CI of the GMT ratio (Comparator/AFLURIA) did not exceed 1.5 and the upper bound of the 2-sided 95% CI of the seroconversion rate difference (Comparator minus AFLURIA) did not exceed 10.0% for each strain. As shown in Table 6, non-inferiority of AFLURIA to the comparator vaccine was demonstrated in the per protocol population for influenza A subtypes H1N1 and H3N2.
and A(H3N2), but not for influenza type B. For influenza type B, non-inferiority was demonstrated for HI GMTs, but not for seroconversion rates. Note that the study was not sufficiently diverse to assess differences between races or ethnicities. The study was powered to assess the pre-specified non-inferiority criteria based on 1400 evaluable subjects. Analysis of the 761 subjects aged 5 through 17 years reduced the power of the study and widened the confidence intervals. In the pre-specified analysis, AFLURIA was not inferior to the comparator vaccine for all three virus strains. Post-hoc analyses of immunogenicity by gender did not demonstrate significant differences between males and females. The study was not sufficiently diverse to assess differences between races or ethnicities. Analyses of immunogenicity by race or ethnicity were not performed prior to vaccination and at 21 days after vaccination. Most of the subjects in the per-protocol immunogenicity population were female (56.7%) and White (97.4%). 2.0% were Black and less than 1.0% were of other races or ethnicities.

The co-primary endpoints were HI GMT ratios (adjusted for baseline HI titers) and the difference in seroconversion rates for each vaccine strain 21 days after vaccination. Pre-specified non-inferiority criteria required that the upper bound of the 2-sided 95% CI of the GMT ratio (Comparator/AFLURIA) did not exceed 1.5 and the upper bound of the 2-sided 95% CI of the seroconversion rate difference (Comparator minus AFLURIA) did not exceed 10.0% for each strain. As shown in Table 9, non-inferiority of AFLURIA to the comparator vaccine was demonstrated in the per protocol population for influenza A subtypes A(H1N1) and A(H3N2), but not for influenza type B. For the B strain, non-inferiority was demonstrated for HI GMTs, but not for seroconversion rates. Post-hoc analyses of immunogenicity by gender did not demonstrate significant differences between males and females. The study was not sufficiently diverse to assess differences between races or ethnicities. The study was powered to assess the pre-specified non-inferiority criteria based on 1400 evaluable subjects.

### Table 7: Post-Vaccination HI Antibody GMTs, Seroconversion Rates, and Analyses of Non-Inferiority of AFLURIA to a U.S.-Licensed Comparator, Subjects 5 through 17 Years of Age (Study 1)

<table>
<thead>
<tr>
<th>Strain</th>
<th>Post-vaccination GMT</th>
<th>Comparator N=381</th>
<th>AFLURIA N=380</th>
<th>Comparator over AFLURIA (95% CI)</th>
<th>Seroconversion %</th>
<th>Comparator minus AFLURIA (95% CI)</th>
<th>Met both pre-defined non-inferiority criteria?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (H1N1)</td>
<td>52.6 507.4</td>
<td>1.03 (0.88, 1.22)</td>
<td>62.7</td>
<td>62.6</td>
<td>0.1 (-6.8, 7.0)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>A (H3N2)</td>
<td>106.0 961.3</td>
<td>1.07 (0.94, 1.23)</td>
<td>72.2</td>
<td>69.7</td>
<td>2.4 (-4.0, 8.9)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>123.3 110.1</td>
<td>1.10 (0.94, 1.29)</td>
<td>75.1</td>
<td>70.0</td>
<td>5.1 (-1.3, 11.4)</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; GMT, geometric mean titer.

### 14.3 IMMUNOGENICITY IN ADULTS AND OLDER ADULTS—ADMINISTRATION VIA NEEDLE AND SYRINGE

Two randomized, controlled clinical studies of AFLURIA evaluated the immune responses by measuring HI antibody titers to each virus strain in the vaccine in adults as compared to placebo (adults 18 through 64 years) or another U.S.-licensed trivalent influenza vaccine (adults ≥ 65 years). In these studies, post-vaccination immunogenicity was evaluated on sera obtained 21 days after administration of a single dose of AFLURIA.

Study 4 was a randomized, double-blind, placebo-controlled, multi-center study in healthy subjects ages 18 through 64 years. A total of 1,357 subjects were vaccinated (1,089 subjects with AFLURIA and 268 with a placebo). Subjects who received AFLURIA were vaccinated using either the preservative-free or thimerosal-containing formulation. The evaluable population consisted of 1,341 subjects (707 in the AFLURIA group and 264 in the placebo group). The mean age of the entire evaluable population receiving AFLURIA was 38 years. 62.5% of subjects were female, 81.3% were White, 12.1% were Black, and 6.2% were Asian.

Serum HI antibody responses to AFLURIA met the pre-specified co-primary endpoint criteria for all three virus strains (Table 8). Similar responses were observed between genders. The study was not sufficiently diverse to assess immunogenicity by race or ethnicity.

### Table 8: Serum Antibody Responses in Subjects 18 through 64 Years of Age Receiving AFLURIA (Study 4)

<table>
<thead>
<tr>
<th>Strain Variable</th>
<th>AFLURIA N=1077 value (95% CI)</th>
<th>Placebo N=264 value (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A(H1N1)</td>
<td>HI Titer ≥ 1:40*</td>
<td>97.8% (96.7, 98.6)</td>
</tr>
<tr>
<td></td>
<td>Seroconversion Rate (%)</td>
<td>48.7% (45.6, 51.7)</td>
</tr>
<tr>
<td>A(H3N2)</td>
<td>HI Titer ≥ 1:40*</td>
<td>99.9% (99.5, 100.0)</td>
</tr>
<tr>
<td></td>
<td>Seroconversion Rate (%)</td>
<td>71.5% (68.7, 74.2)</td>
</tr>
<tr>
<td>B</td>
<td>HI Titer ≥ 1:40*</td>
<td>94.2% (92.7, 95.6)</td>
</tr>
<tr>
<td></td>
<td>Seroconversion Rate (%)</td>
<td>69.7% (66.9, 72.5)</td>
</tr>
</tbody>
</table>

* HI titer ≥ 1:40 is defined as the proportion of subjects with a minimum post-vaccination HI antibody titer of 1:40. Lower bound of 95% CI for HI antibody titer ≥ 1:40 should be > 70% for the study population.

### 14.4 IMMUNOGENICITY IN ADULTS—ADMINISTRATION VIA PHARMAJET STRATIS NEEDLE-FREE INJECTION SYSTEM

Study 7 was a randomized, comparator-controlled non-inferiority study that enrolled 1,250 subjects 18 through 64 years of age. This study compared the immune response following administration of AFLURIA when delivered IM using either the Pharmatek Stratts Needle-Free Injection System or needle and syringe. Immunogenicity assessments were performed prior to vaccination and at 28 days after vaccination in the immunogenicity population (1130 subjects, 562 Pharmatek Stratts Needle-Free Injection System group, 568 needle and syringe group). The co-primary endpoints were HI GMT ratios for each vaccine strain and the absolute difference in seroconversion rates for each vaccine strain 28 days after vaccination. As shown in Table 10, non-inferiority of administration of AFLURIA by the Pharmatek Stratts Needle-Free Injection System compared to administration of AFLURIA by needle and syringe was demonstrated in the immunogenicity population for all strains. Post-hoc analyses of immunogenicity by age showed that younger subjects (18 through 49 years) elicited higher immunological responses than older subjects (50 through 64 years). Post-hoc analyses of immunogenicity according to gender and body mass index did not reveal significant influences of these variables on immune responses. The study population was not sufficiently diverse to assess immunogenicity by race or ethnicity.
Table 10: Baseline and Post-Vaccination HI Antibody GMTs, Seroconversion Rates, and Analyses of Non-Inferiority of AFLURIA Administered by PharmaJet Stratis Needle-Free Injection System or Needle and Syringe, Adults 18 through 64 Years of Age (Study 7)

<table>
<thead>
<tr>
<th>Strain</th>
<th>Baseline GMT</th>
<th>Post-vaccination GMT</th>
<th>GMT Ratio (^a)</th>
<th>Seroconversion % (^b)</th>
<th>Difference</th>
<th>Met both pre-defined non-inferiority criteria? (^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Needle and Syringe N=568</td>
<td>PharmaJet Stratis Needle-Free Injection System N=562</td>
<td>Needle and Syringe N=568</td>
<td>PharmaJet Stratis Needle-Free Injection System N=562</td>
<td>Needle and Syringe minus PharmaJet Stratis Needle-Free Injection System (95% CI)</td>
<td></td>
</tr>
<tr>
<td>A(H1N1)</td>
<td>79.5</td>
<td>83.7</td>
<td>280.6</td>
<td>282.9</td>
<td>0.99</td>
<td>(0.88, 1.12)</td>
</tr>
<tr>
<td></td>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A(H3N2)</td>
<td>75.4</td>
<td>68.1</td>
<td>265.9</td>
<td>247.3</td>
<td>1.08</td>
<td>(0.96, 1.21)</td>
</tr>
<tr>
<td></td>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>12.6</td>
<td>13.5</td>
<td>39.7</td>
<td>42.5</td>
<td>0.94</td>
<td>(0.83, 1.06)</td>
</tr>
<tr>
<td></td>
<td>(95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; GMT, geometric mean titer

\(^a\) GMT ratio is defined as post-vaccination GMT for Needle and Syringe/PharmaJet Stratis Needle-Free Injection System

\(^b\) Seroconversion rate is defined as a 4-fold increase in post-vaccination HI antibody titer from pre-vaccination titer ≥ 1:10 or an increase in titer from < 1:10 to ≥ 1:40.

\(^c\) Non-inferiority (NI) criteria for the GMT ratio: upper bound of 2-sided 95% CI on the ratio of Needle and Syringe/PharmaJet Stratis Needle-Free Injection System. GMT should not exceed 1.5. NI criteria for the seroconversion rate (SCR) difference: upper bound of 2-sided 95% CI on the difference between SCR Needle and Syringe – SCR PharmaJet Stratis Needle-Free Injection System should not exceed 10%.

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING
16.1 HOW SUPPLIED
Each product presentation includes a package insert and the following components:

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Carton NDC Number</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Filled Syringe</td>
<td>33332-014-01</td>
<td>• Ten 0.5 mL single-dose syringes without needles</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• [NDC 33332-014-02]</td>
</tr>
<tr>
<td>Multi-Dose Vial</td>
<td>33332-114-10</td>
<td>• One 5 mL vial, which contains ten 0.5 mL doses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• [NDC 33332-114-11]</td>
</tr>
</tbody>
</table>

16.2 STORAGE AND HANDLING
• Store refrigerated at 2-8°C (36-46°F).
• Do not freeze. Discard if product has been frozen.
• Protect from light.
• Do not use AFLURIA beyond the expiration date printed on the label.
• Once the stopper of the multi-dose vial has been pierced the vial must be discarded within 28 days.

17 PATIENT COUNSELING INFORMATION
• Inform the vaccine recipient or guardian of the potential benefits and risks of immunization with AFLURIA.
• Inform the vaccine recipient or guardian that AFLURIA is an inactivated vaccine that cannot cause influenza but stimulates the immune system to produce antibodies that protect against influenza, and that the full effect of the vaccine is generally achieved approximately 3 weeks after vaccination.
• Instruct the vaccine recipient or guardian to report any severe or unusual adverse reactions to their healthcare provider.
• Provide the vaccine recipient or guardian with Vaccine Information Statements which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).
• Instruct the vaccine recipient or guardian that annual revaccination is recommended.

Manufactured by:
bioCSL Pty Ltd.
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US License No. 1764

Distributed by:
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