





**B. Patient Information:**

State the name of the patient (Diet Drug Recipient) for whom you are providing the information contained in this form.

\_\_\_\_\_ (First Name of Diet Drug Recipient)    \_\_\_\_\_ (Middle Initial)    \_\_\_\_\_ (Last Name)

C. 1. Did the above-named patient have an Echocardiogram which was conducted in accordance with the standards and criteria as outlined in Feigenbaum<sup>2</sup> (1994) or Weyman<sup>3</sup> (1994)?

- Yes     No

2. If the answer to Question C.1 is "Yes," state the date when the Echocardiogram was performed.

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ (MM/DD/YYYY)

3. Based on your review of the Echocardiogram tape or disk, does the above-named Diet Drug Recipient have the following conditions as defined by Singh<sup>4</sup>? (Check each that applies):

- a. For **mitral** regurgitation, the following determined in any apical view:
 Mild mitral regurgitation, defined as (1) either the regurgitant jet area/left atrial area ("RJA/LAA") ratio is more than 5% or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than 20%.
 Moderate mitral regurgitation, defined as regurgitant jet area in any apical view equal to or greater than 20% of the left atrial area but less than or equal to 40% (20%-40% RJA/LAA).
 Severe mitral regurgitation, defined as > 40% RJA/LAA.
 None of the above.
b. For **aortic** regurgitation, the following determined in the parasternal long-axis view or in the apical long-axis view, if the parasternal long-axis view is unavailable:
 Mild aortic regurgitation, defined as regurgitant jet diameter equal to or greater than 10% but less than 25% of the outflow tract height (10%-24% jet height ("JH")/left ventricular outflow tract height ("LVOTH")).
 Moderate aortic regurgitation, defined as 25%-49% JH/LVOTH.
 Severe aortic regurgitation, defined as > 49% JH/LVOTH.
 None of the above.

**D. Based on your review of the Echocardiogram tape or disk (or the results of any cardiac catheterization or surgical examination), does the above-named Diet Drug Recipient have any of the following conditions:**

- 1. Congenital Aortic Valve Abnormalities: Unicuspid, Bicuspid or Quadricuspid aortic valve; ventricular septal defect associated with aortic regurgitation?
 Yes     No
2. Aortic dissection involving the aortic root and/or aortic valve?
 Yes     No
3. Aortic sclerosis at the time that the Diet Drug Recipient was first diagnosed with mild or greater aortic regurgitation if he or she was 60 or older at that time?
 Yes     No

<sup>2</sup> H. Feigenbaum, *Echocardiography* 68-133 (5th ed. 1994).
<sup>3</sup> A. E. Weyman, *Principles and Practice of Echocardiography* 75-97 (2d ed. 1994).
<sup>4</sup> J. P. Singh, et al., *Prevalence and Clinical Determinants of Mitral, Tricuspid and Aortic Regurgitation (The Framingham Heart Study)*, 83 Am. J. Cardiol. 897-902 (1999).





4. Aortic root dilation >5.0 cm?  
 Yes       No
5. Aortic stenosis with an aortic valve area <1.0 square centimeter by the Continuity Equation?  
 Yes       No
6. Congenital mitral valve abnormalities: Parachute valve or cleft of the mitral valve associated with atrial septal defect?  
 Yes       No
7. Mitral valve prolapse defined as a condition where (a) the Echocardiogram videotape or disk includes the parasternal long-axis view and (b) that Echocardiographic view shows displacement of one or both mitral leaflets >2 mm above the atrial-ventricular border during systole, and >5 mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist<sup>5</sup>?  
 Yes       No
8. Chordae tendinae rupture or papillary muscle rupture, or acute myocardial infarction associated with acute mitral regurgitation?  
 Yes       No
9. Mitral annular calcification?  
 Yes       No
10. M-Mode and 2-D Echocardiographic evidence of rheumatic heart valves (doming of the anterior leaflet and/or anterior motion of the posterior leaflet and/or commissural fusion), except where a Board-Certified Pathologist has examined mitral valve tissue and determined that there was no evidence of rheumatic valve disease?  
 Yes       No

**E. To the best of your knowledge, has the above-named Diet Drug Recipient had the following:**

1. Heart valve surgery to repair or replace the mitral valve prior to Pondimin<sup>®</sup> and/or Redux<sup>™</sup> use?  
 Yes       No
2. Heart valve surgery to repair or replace the aortic valve prior to Pondimin<sup>®</sup> and/or Redux<sup>™</sup> use?  
 Yes       No
3. Bacterial endocarditis prior to Pondimin<sup>®</sup> and/or Redux<sup>™</sup> use?  
 Yes       No
4. Mild or greater aortic regurgitation confirmed by echocardiography prior to Pondimin<sup>®</sup> and/or Redux<sup>™</sup> use?  
 Yes       No
5. Moderate or greater mitral regurgitation confirmed by echocardiography prior to Pondimin<sup>®</sup> and/or Redux<sup>™</sup> use?  
 Yes       No
6. Carcinoid tumor of a type associated with aortic and/or mitral valve lesions?  
 Yes       No
7. History of daily use of methysergide or ergotamines for a continuous period of longer than 120 days?  
 Yes       No

<sup>5</sup> L.A. Freed, et al., *Prevalence and Clinical Outcomes of Mitral Valve Prolapse*, 341 New Eng. J. Med. 1, 2 (1999).





- 8. A diagnosis of Systemic Lupus Erythematosus and valvular regurgitation and/or abnormalities of a type associated with Systemic Lupus Erythematosus?<sup>6</sup>  
 Yes       No
- 9. A diagnosis of rheumatoid arthritis and valvular regurgitation and/or abnormalities of a type associated with rheumatoid arthritis?<sup>7</sup>  
 Yes       No

**F. To the best of your knowledge, has the above-named Diet Drug Recipient developed the following conditions after the date on which the patient first used Pondimin® and/or Redux™:**

- 1. Bacterial endocarditis associated with either mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation? [If “Yes,” documentation supporting bacterial endocarditis must be provided.]  
 Yes       No
- 2. Pulmonary Hypertension secondary to **severe aortic regurgitation** with a peak systolic pulmonary pressure >40 mm Hg<sup>8</sup> measured by cardiac catheterization or with a peak systolic pulmonary artery pressure >45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures<sup>9,10</sup> assuming a right atrial pressure of 10 mm Hg?  
 Yes       No
- 3. Pulmonary Hypertension secondary to moderate or greater mitral regurgitation with peak systolic pulmonary artery pressure >40 mm Hg measured by cardiac catheterization or with a peak systolic pulmonary artery pressure >45 mm Hg<sup>11</sup> measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg?  
 Yes       No
- 4. Abnormal left ventricular end-systolic dimension >50 mm<sup>12</sup> by M-mode or 2-D echocardiography or abnormal left ventricular end-diastolic dimension >70<sup>13</sup> mm as measured by M-mode or 2-D echocardiography?  
 Yes       No
- 5. Abnormal left atrial supero-inferior systolic dimension >5.3 cm<sup>14</sup> (apical four chamber view) or abnormal left atrial antero-posterior systolic dimension >4.0 cm (parasternal long-axis view) measured by 2-D directed M-mode or 2-D echocardiography with normal sinus rhythm using sites of measurement recommended by the American Society of Echocardiography?<sup>15</sup>  
 Yes       No

<sup>6</sup> *Harrison's Principles of Internal Medicine* 1878 (14th ed. 1998).

<sup>7</sup> *Id.* at 1885.

<sup>8</sup> Braunwald, *Heart Disease: Textbook of Cardiovascular Medicine* 796-98 (1997).

<sup>9</sup> Feigenbaum, *supra* at 201-02.

<sup>10</sup> Chan, K-L., *et al.*, *Comparison of Three Doppler Ultrasound Methods in the Prediction of Pulmonary Artery Disease*, 9 J. Am. Coll. Cardiol. 549-554 (1987).

<sup>11</sup> Braunwald, *supra*.

<sup>12</sup> Bonow R.O., *et al.*, *Guidelines for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Management of Patients With Valvular Heart Disease)*, 32 J. Am. Coll. Cardiol. 1510-14 (1998).

<sup>13</sup> *Id.*

<sup>14</sup> Weyman, *supra* at 1290-1292.

<sup>15</sup> Henry, W.L. *et al.*, *Report of the American Society of Echocardiography Committee on Nomenclature and Standards in Two-dimensional Echocardiography*, 62 *Circulation* 212-17 (1980).





6. Abnormal left ventricular end-systolic dimension greater than or equal to 45 mm<sup>16</sup> by M-mode or 2-D Echocardiogram?

Yes       No

7. Arrhythmias, defined as chronic atrial fibrillation/flutter that cannot be converted to normal sinus rhythm, or atrial fibrillation/flutter requiring ongoing medical therapy, either of which are associated with left atrial enlargement? (Abnormal left atrial supero-inferior systolic dimension >5.3 cm<sup>17</sup> (apical four chamber view) or abnormal left atrial antero-posterior systolic dimension >4.0 cm (parasternal long-axis view) measured by 2-D directed M-mode or 2-D echocardiography.)

Yes       No

8. Ejection fractions as follows:<sup>18</sup>

50% – 60%	<input type="checkbox"/> Yes	<input type="checkbox"/> No	30% – 34%	<input type="checkbox"/> Yes	<input type="checkbox"/> No
40% – 49%	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<30%	<input type="checkbox"/> Yes	<input type="checkbox"/> No
35% – 39%	<input type="checkbox"/> Yes	<input type="checkbox"/> No			

9. Surgery to repair or replace the aortic and/or mitral valve(s) **after** use of Pondimin<sup>®</sup> and/or Redux<sup>™</sup>?

Yes       No

10. Severe regurgitation and the presence of ACC/AHA Class I indications for surgery to repair or replace the aortic<sup>19</sup> and/or mitral<sup>20</sup> valve(s) where such surgery was not performed?

Yes       No

a. Was valvular repair/replacement surgery medically indicated but the patient declined to consent to surgery?

Yes       No

b. Was valvular repair/replacement surgery medically contraindicated?

Yes       No

**If your answer to Question F.10 was “Yes,” supply (at end of form) or attach a written statement from the attending Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon supported by medical records regarding the recommendation made to the patient concerning valvular surgery with the reason that surgery was not performed.**

11. Stroke due to (a) bacterial endocarditis contracted after use of Pondimin<sup>®</sup> and/or Redux<sup>™</sup>, or (b) chronic atrial fibrillation with left atrial enlargement as defined in Question F.5 above, or (c) valvular repair and/or replacement surgery which has resulted in a permanent condition which meets the criteria for the following functional levels of the AHA Stroke Outcome Classification System,<sup>21</sup> determined six months or later after the event:

a. Functional Level II	<input type="checkbox"/> Yes	<input type="checkbox"/> No
b. Functional Level III	<input type="checkbox"/> Yes	<input type="checkbox"/> No
c. Functional Level IV	<input type="checkbox"/> Yes	<input type="checkbox"/> No
d. Functional Level V	<input type="checkbox"/> Yes	<input type="checkbox"/> No

<sup>16</sup> Bonow, *supra* at 1533-35.  
<sup>17</sup> Weyman, *supra* at 1290-1292.  
<sup>18</sup> Bonow, *supra*.  
<sup>19</sup> Bonow, *supra* at 1510-14.  
<sup>20</sup> Bonow, *supra* at 1533-35.

<sup>21</sup> M. Kelley-Hayes, *et al.*, *The American Heart Association Stroke Outcome Classification*, 29 *Stroke* 1274-80, 1275 (1998). (Note: approved by the American Heart Association Science Advisory and Coordinating committee.)





- 12. A peripheral embolus due to bacterial endocarditis and/or as a consequence of atrial fibrillation with left atrial enlargement as defined above which resulted in:
  - a. Severe impairment to the kidneys, defined as chronic severe renal failure requiring hemodialysis or Continuous Abdominal Peritoneal Dialysis for more than six months.  
 Yes       No
  - b. Severe impairment to the abdominal organs, defined as impairment requiring intra-abdominal surgery.  
 Yes       No
  - c. Severe impairment to the extremities, defined as impairment requiring amputation of a major limb.  
 Yes       No

**G. Does the above-named Diet Drug Recipient have New York Heart Association Functional Class symptoms as follows:**

- 1. Class I       Yes       No      3. Class III       Yes       No
- 2. Class II       Yes       No      4. Class IV       Yes       No

**If the individual has such symptoms, supply documentation of these symptoms as documented by the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist.**

**H. Did the above-named Diet Drug Recipient have valvular repair or replacement surgery and have one or more of the following complications either during surgery, within 30 days after surgery, or during the same hospital stay as surgery:**

- 1. Renal failure, defined as chronic, severe renal failure requiring regular hemodialysis or Continuous Abdominal Peritoneal Dialysis (CAPD) for greater than six months following aortic and/or mitral valve replacement surgery?  
 Yes       No
- 2. Peripheral embolus following surgery resulting in severe permanent impairment of the kidneys, abdominal organs, or extremities? NOTE: Severe permanent impairment of the kidneys means chronic severe renal failure requiring hemodialysis or continuous abdominal peritoneal dialysis for more than six months. Severe impairment of the abdominal organs means impairment requiring intra-abdominal surgery. Severe impairment of the extremities means impairment requiring amputation of a major limb.  
 Yes       No
- 3. Quadriplegia or paraplegia resulting from cervical spine injury during valvular heart surgery?  
 Yes       No

**I. Did the above-named Diet Drug Recipient have valve repair or replacement surgery and have:**

- 1. Post-operative endocarditis, mediastinitis or sternal osteomyelitis, any of which required reopening of the median sternotomy for treatment?  
 Yes       No
- 2. A post-operative serious infection defined as HIV or Hepatitis C within six months of surgery as a result of blood transfusion associated with the surgery?  
 Yes       No





**J. Did the above-named Diet Drug Recipient have valvular repair or replacement surgery and require a second surgery through the sternum within 18 months of the initial surgery due to prosthetic valve malfunction, poor fit, or complications reasonably related to the initial surgery?**

- Yes       No

**K. Did the above-named Diet Drug Recipient have valvular repair or replacement surgery and have a left ventricular ejection fraction of < 40% at any time six months or later after the valvular repair or replacement surgery?**

- Yes       No

**If your answer to Question K was “Yes,” an Echocardiogram report and Echocardiogram tape or disk performed and interpreted in accordance with the standards and criteria outlined in Question C.1 above must be furnished.**

**L. Did the above-named Diet Drug Recipient have one or more of the following:**

1. A heart transplant?

- Yes       No

2. Irreversible pulmonary hypertension secondary to valvular heart disease defined as peak-systolic pulmonary artery pressure >50 mm Hg<sup>22</sup> (by cardiac catheterization), at rest, following repair or replacement surgery of the aortic and/or mitral valve(s)?

- Yes       No

3. A persistent non-cognitive state<sup>23</sup> caused by a complication of valvular heart disease (e.g., cardiac arrest) or valvular repair/replacement surgery?

- Yes       No

**If the individual has such a condition, supply a detailed statement of the attending Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon supported by medical records setting forth the basis for your opinion that the persistent non-cognitive state was caused by a complication of valvular heart disease or valvular repair/replacement surgery.**

4. Death resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery?

- Yes       No

**Supply a detailed statement of the attending Board-Certified Cardiologist or Board-Certified Cardiothoracic Surgeon supported by medical records setting forth your opinion that the patient’s death resulted from a condition caused by valvular heart disease and/or valvular repair/replacement surgery.**

5. Ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise?

- Yes       No

<sup>22</sup> Braunwald, *supra* at 596-98.

<sup>23</sup> Adelman, G., *Encyclopedia of Neuroscience* 268 (1987).





