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## Appendix A: National Panel of Experts, 2001

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## Appendix B: Commonly Asked Questions and Recommended Answers

Question by Pharmacy Staff	Answer by Patient-Observer
Hello, can I help you?	Yes, would you fill these prescriptions for me.
Have you filled prescriptions here before?	No.
What is your name?	(assigned name)
What is your birth date?	(your modified birth date)
What is your address?	(your modified address)
Are you visiting?	Yes, I am.
What is your telephone number?	(your modified telephone number)
How will you pay for the prescriptions?	I will pay with cash.
Do you have prescription insurance?	No.
Do you have any other medical conditions?	No, just some heart disease and diabetes.
Do you take any other prescription medications?	No, I am not taking any other medications.
Do you have any allergies to medications?	No, none that I know of.
Have you been taking any over-the-counter or non-prescription medications?	No, I haven't been taking any medications.
Is this the first time you have taken any of these medications?	Yes, it's the first time I've taken any of these.
What did the doctor tell you about the medications?	Just that the directions would be on the label.
When are you talking with the doctor next?	I will be seeing the doctor in two weeks.
What will you do if you have any problems with the medication?	I will call my doctor.
What will you do if your health does not improve?	I will call my doctor.
For what reason did doctor prescribe glyburide (or Micronase or Diabeta)?	My diabetes (If pressed say: the doctor said my blood sugar was up)
For what reason did doctor prescribe Lipitor® (or atorvastatin)?	I think for cholesterol (If pressed say: the doctor said it was too high)
For what reason did doctor prescribe nitroglycerin?	For chest pain (If pressed say: I had difficulty breathing)
For what reason did doctor prescribe the atenolol (Tenormin)?	Doctor said I had some heart disease (If pressed say: That's about all I know)

## Appendix B: Commonly Asked Questions and Recommended Answers

Question by Pharmacy Staff	Answer by Patient-Observer
What tests did you have at the hospital?	They did stress test (treadmill).
Do you monitor your diabetes?	No.
Do you follow any special diet?	Yes, for my diabetes.
Do you exercise?	Yes, I walk 20-30 minutes a day.
Did the doctor tell you to take aspirin?	No, we didn't discuss that.
Have you had any other symptoms?	Just chest pain and shortness of breath
Atenolol can cause problems with blood sugar. Did your doctor mention this?	The doctor mentioned something about that, but said it was important for me to take it.
Did the doctor give you any "samples" of the medication?	No.
Would you like pharmacist to counsel you?	Sure
Would you like written information about the medication?	Sure

### Additional Things to Do and Avoid as a Patient-Observer

#### THINGS TO DO

- Make your approach and presentation in each pharmacy as identical as possible.
- Be polite and act interested in what is said to you.
- Accept whatever information is offered.
- Answer questions briefly and clearly as directed by your standard scenario. If asked for your Social Security number, respond: "I prefer not to give it."
- Ask what time your prescription will be ready.
- Place medication, receipt, and written materials into the pharmacy's envelope for the project director.
- Consider yourself a passive patient.

#### THINGS TO AVOID

- Do not volunteer any information unless you are asked.
- Do not ask any questions after determining when your prescriptions will be ready.
- Do not initiate any "small talk" with pharmacy personnel.
- Do not argue if the legitimacy of your prescriptions or you as a patient are questioned. If this happens, politely say, "I'm sorry to inconvenience you. I will fill the prescriptions at home." After leaving pharmacy, inform your project director.
- If no one offers counseling, do not ask for it.
- If no one offers written information, do not ask for it.

**Appendix C1: Patient Information Evaluation Form – ATENOLOL**

Office Use: Pharmacy ID: \_\_\_ Rater ID: \_\_ Leaflet ID: \_\_\_\_\_

**Rater:** Check two boxes ✓✓ if sub-criterion is fully or nearly fully met. Other wording may be counted if it is equivalent or similar in meaning.  
 Check one box ✓ if sub-criterion is partially met. Leave both boxes blank if no information is provided. PR= doctor or other prescriber; PH= pharmacist

**Criteria 1-6: Information is sufficiently specific and comprehensive.**

<p><b>1. Drug names and indications for use</b></p> <p>1.1 generic name: atenolol ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.2 phonetic spelling of generic name ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.3 brand names: Tenormin ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.4 drug class :beta-blocker or beta-adrenergic blocking agent ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.5 treat hypertension (or high blood pressure) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.6 treat angina (or chest pain) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.7 treat definite or suspected myocardial infarction (or heart attack) .... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>4. Specific precautions and how to avoid harm while using it</b></p> <p>4.1 Tell PR or PH if you take <u>any other medications</u>, especially: ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.2 calcium channel blockers such as verapamil and diltiazem ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.3 other blood pressure medicines such as clonidine ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.4 over-the-counter cold products or decongestants ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.5 <u>Do not stop suddenly</u>; gradual dose reduction may be needed# ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.6 May cause serious reaction to <u>allergy shots</u>; tell PR before shots ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.7 May worsen <u>allergic reaction</u> to foods, medicines, or stings; tell PR as soon as possible so it can be treated ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.8 Before <u>surgery</u>, tell PR or dentist you are taking this medicine ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.9 May affect <u>blood sugar</u> or cover up signs of low blood sugar ..... <input type="checkbox"/> <input type="checkbox"/></p> <p># information derived from “black box” warning on professional labeling</p> <p>Comment:</p>
<p><b>2. Contraindications and what to do before using drug</b></p> <p>Tell PR or PH if you have:</p> <p>2.1 certain heart problems (or: heart failure, very slow heartbeat) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.2 asthma or emphysema ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.3 diabetes ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.4 overactive thyroid ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.5 poor circulation ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if you are:</p> <p>2.6 <u>pregnant</u> or may become pregnant; can cause harm to baby ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.7 <u>nursing</u> or breast-feeding ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>5. Symptoms of serious or frequent adverse reactions and what to do</b></p> <p>Tell PR or PH as soon as possible if any of these occur:</p> <p>5.1 trouble breathing ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.2 cold hands or feet ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.3 slow heartbeat or fainting ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.4 swelling of legs or ankles/feet ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if any of these do not go away or bother you:</p> <p>5.5 feeling dizzy ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.6 feeling tired ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.7 feeling depressed ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.7 trouble having sex ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.8 trouble sleeping ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>

**Criteria 1-6: Information is sufficiently specific and comprehensive.**

<p><b>3. Specific directions about how to use, monitor, and get most benefit</b></p> <p>3.1 It is important to take this medicine <u>regularly</u> to get the most benefit . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.2 To help you remember, take it the <u>same time(s)</u> each day . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.3 If you <u>miss a dose</u>, take it as soon as you remember . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.4 Skip missed dose if next scheduled dose is less than 8 hours away . . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.5 Do not take two doses at same time (or: do not double up) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.6 May take with or without <u>food</u> . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.7 <u>Store</u> at room temperature, away from excess heat and moisture . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>6. General information and encouragement to ask questions</b></p> <p>6.1 Keep all medicines <u>away from children</u> . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>6.2 Do not give this medicine to <u>others</u> . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>6.3 Leaflet states that it <u>does not include all</u> uses, precautions, interactions, adverse reactions, or side effects . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>6.4 Name of <u>publisher</u> . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>6.5 <u>Date</u> of publication or most recent revision . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>6.6 Ask PR or PH <u>if any questions</u> or concerns . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>6.7 You may ask PH for <u>longer leaflet</u> written for professionals . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p align="center">*****GO TO PAGE 2*****</p> <p>Comment:</p>
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<p><b>Criteria 7: Information is scientifically accurate, unbiased, up-to-date</b></p> <p>7.1 information is neutral in content and tone . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.2 no unapproved uses are listed (see 1.0 for approved uses) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.3 no promotional messages about a specific brand, manufacturer, or distributor (may compare chemical entities) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.4 no inaccurate or outdated claims about benefits of product . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.5 no inaccurate or outdated claims about risks of product . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.6 no other inaccurate or outdated information was found by this rater . . <input type="checkbox"/> <input type="checkbox"/></p> <p>NOTE: All items should be completed even if no information is provided about the uses, benefits, or risks of a product. The purpose is to identify inaccurate, biased, and/or outdated information</p> <p>Comment:</p>	<p><b>Criterion 8: Information is readily comprehensible and legible.</b></p> <p>8.1 black box warning information printed in bold-face type or box . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.2 minimal use of italics or ornate typefaces that are hard to read . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.3 upper and lower case lettering . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.4 headings placed on separate lines (not on same line as text) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.5 bullets used to enhance readability . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.6 information is well organized and easy to find . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p> <p><u>The following will be assessed by office staff – leave boxes blank</u></p> <p>8.7 adequate space between lines (<math>\geq 2.2</math> mm; this is approx. 2.2mm) . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.8 used no smaller than 10-point type (this is 10-point) . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.9 good ink-paper contrast . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.10 written at 6-8th grade level (excluding drug names) . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p># none applicable for this drug * will be assessed by office staff, leave blank</p>
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**Appendix C2: Patient Information Evaluation Form – GLYBURIDE**

Office Use: Pharmacy ID: \_\_\_ Rater ID: \_\_ Leaflet ID: \_\_\_\_\_

**Rater:** Check two boxes ✓✓ if sub-criterion is fully or nearly fully met. Other wording may be counted if it is equivalent or similar in meaning.  
 Check one box ✓ if sub-criterion is partially met. Leave both boxes blank if no information is provided. PR= doctor or other prescriber; PH= pharmacist

<b>Criteria 1-6: Information is sufficiently specific and comprehensive.</b>	
<p><b>1. Drug names and indications for use</b></p> <p>1.1 generic name: glyburide ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.2 phonetic spelling of generic name ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.3 common brand names: DiaBeta, Micronase, Glynase ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.4 antidiabetic (or used to treat diabetes) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.5 sulfonylurea ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.6 used to lower blood sugar ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.7 used in patients whose diabetes cannot be controlled by diet ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.8 used for non-insulin dependent (or Type 2) diabetes ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>4. Specific precautions and how to avoid harm while using it</b></p> <p>4.1 Tell PR or PH before taking <u>any other medications</u>, especially: .... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.2 aspirin products ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.3 anticoagulants (or blood thinners) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.4 azole antifungals (eg, fluconazole) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.5 beta blockers ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.6 diuretics (water pills) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.7 corticosteroids ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.8 MAO inhibitors ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.9 May increase <u>sensitivity to sun</u>; reduce exposure to sun ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>
<p><b>2. Contraindications and what to do if applicable</b></p> <p>Tell PR or PH if you are:</p> <p>2.1 <u>allergic</u> to glyburide or other sulfonylureas ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.2 <u>pregnant</u> or may become pregnant ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.3 <u>nursing</u> or breast-feeding ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Other:</p> <p>2.4 use of other sulfonylurea drugs has been associated with serious heart problems. This risk may apply to use of glyburide ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>5. Symptoms of serious or frequent adverse reactions and what to do</b></p> <p>5.1 May cause <u>low blood sugar</u> or hypoglycemia ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.2 To help prevent, do not miss meals or drink alcohol ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.3 Some symptoms of low blood sugar: fast heartbeat, sweating, tremors, headache, confusion, nervousness [list 3] ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.4 Use quick-acting sugar to treat low blood sugar ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH as soon as possible <u>if any of the following occurs</u>:</p> <p>5.5 allergic reaction: fever, chills, rash, trouble breathing [list 2] ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.6 dark urine, unusual bleeding/bruising, yellowing of eyes [list 2] .... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if any of these <u>do not go away or bother you</u>:</p> <p>5.7 stomach discomfort, pain, fullness [list 1] ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.8 diarrhea ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.9 more frequent urination ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>[Number in brackets shows number of symptoms to be listed for full credit]</p> <p>Comment:</p>

**Criteria 1-6: Information is sufficiently specific and comprehensive.**

<p><b>3. Specific directions about how to use, monitor, and get most benefit</b></p> <p>3.1 It is important to take this medicine <u>regularly</u> to get the most benefit <input type="checkbox"/> <input type="checkbox"/></p> <p>3.2 To help you remember, take it at the <u>same time(s)</u> each day <input type="checkbox"/> <input type="checkbox"/></p> <p>3.3 May take with or without <u>food</u> <input type="checkbox"/> <input type="checkbox"/></p> <p>3.4 If you <u>miss a dose</u>, take it as soon as possible <input type="checkbox"/> <input type="checkbox"/></p> <p>3.5 Skip missed dose if next scheduled dose is less than 8 hours away <input type="checkbox"/> <input type="checkbox"/></p> <p>3.6 Do not double up or take two doses at the same time <input type="checkbox"/> <input type="checkbox"/></p> <p>3.7 Regular <u>testing of blood glucose</u> is important <input type="checkbox"/> <input type="checkbox"/></p> <p>3.8 Important to follow proper <u>diet and exercise</u> program <input type="checkbox"/> <input type="checkbox"/></p> <p>3.9 <u>Store</u> at room temperature, away from excess heat and moisture <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>6. General information and encouragement to ask questions</b></p> <p>6.1 Keep all medicines <u>away from children</u> <input type="checkbox"/> <input type="checkbox"/></p> <p>6.2 Do not give this medicine to <u>others</u> <input type="checkbox"/> <input type="checkbox"/></p> <p>6.3 Leaflet states that it does <u>not include all</u> uses, precautions, interactions, adverse reactions, or side effects <input type="checkbox"/> <input type="checkbox"/></p> <p>6.4 Name of <u>publisher</u> <input type="checkbox"/> <input type="checkbox"/></p> <p>6.5 <u>Date</u> of publication or most recent revision <input type="checkbox"/> <input type="checkbox"/></p> <p>6.6 Ask PR or PH <u>if any questions</u> or concerns <input type="checkbox"/> <input type="checkbox"/></p> <p>6.7 You may ask PH for <u>longer leaflet</u> written for professionals <input type="checkbox"/> <input type="checkbox"/></p> <p align="center">*****GO TO PAGE 2*****</p> <p>Comment:</p>
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<p><b>Criterion 7: Information is scientifically accurate, unbiased, up-to-date</b></p> <p>7.1 information is neutral in content and tone <input type="checkbox"/> <input type="checkbox"/></p> <p>7.2 no unapproved uses are listed (see 1.0 for approved uses) <input type="checkbox"/> <input type="checkbox"/></p> <p>7.3 no promotional messages about a specific brand, manufacturer, or distributor (may compare chemical entities) <input type="checkbox"/> <input type="checkbox"/></p> <p>7.4 no inaccurate or outdated claims about benefits of product <input type="checkbox"/> <input type="checkbox"/></p> <p>7.5 no inaccurate or outdated claims about risks of product <input type="checkbox"/> <input type="checkbox"/></p> <p>7.6 no other inaccurate or outdated information was found by this rater <input type="checkbox"/> <input type="checkbox"/></p> <p>NOTE: All items should be completed even if no information is provided about the uses, benefits, or risks of a product. The purpose is to identify inaccurate, biased, and/or outdated information</p> <p>Comment:</p>	<p><b>Criterion 8: Information is readily comprehensible and legible.</b></p> <p>8.1 black box warning information printed in bold-face type or box <input type="checkbox"/> NA #</p> <p>8.2 minimal use of italics or ornate typefaces that are hard to read <input type="checkbox"/> <input type="checkbox"/></p> <p>8.3 upper and lower case lettering <input type="checkbox"/> <input type="checkbox"/></p> <p>8.4 headings placed on separate lines (not on same line as text) <input type="checkbox"/> <input type="checkbox"/></p> <p>8.5 bullets used to enhance readability <input type="checkbox"/> <input type="checkbox"/></p> <p>8.6 information is well organized and easy to find <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p> <p><u>The following will be assessed by office staff – leave boxes blank</u></p> <p>8.7 adequate space between lines (<math>\geq 2.2</math> mm; this is approx. 2.2mm) <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.8 used no smaller than 10-point type (this is 10-point) <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.9 good ink-paper contrast <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.10 written at 6-8th grade level (excluding drug names) <input type="checkbox"/> <input type="checkbox"/> *</p> <p># none applicable for this drug * will be assessed by office staff, leave blank</p>
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**Appendix C3: Patient Information Evaluation Form – ATORVASTATIN**

Office Use: Pharmacy ID: \_\_\_ Rater ID: \_\_\_ Leaflet ID: \_\_\_\_\_

**Rater:** Check two boxes   if sub-criterion is fully or nearly fully met. Other wording may be counted if it is equivalent or similar in meaning.  
 Check one box  if sub-criterion is partially met. Leave both boxes blank if no information is provided. PR= doctor or other prescriber; PH= pharmacist

<b>Criteria 1-6: Information is sufficiently specific and comprehensive.</b>	
<p><b>1. Drug names and indications for use</b></p> <p>1.1 generic name: atorvastatin ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.2 phonetic spelling of generic name ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.3 brand name: Lipitor ..... <input type="checkbox"/> <input type="checkbox"/> 1.4</p> <p>drug class: HMG - CoA reductase inhibitors ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.5 used to lower cholesterol levels ..... <input type="checkbox"/> <input type="checkbox"/> 1.6</p> <p>used in persons whose cholesterol levels cannot be controlled with proper diet, exercise, and weight loss if overweight. .... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>4. Specific precautions and how to avoid harm while using it</b></p> <p>4.1 Tell PR or PH before taking any <u>other medications</u>, especially: ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.2 immunosuppressants, especially cyclosporine (Sandimmune) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.3 gemfibrozil (Lopid) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.4 erythromycin ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.5 niacin (nicotinic acid) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.6 azole antifungals (eg fluconazole, ketoconazole, or itraconazole) ... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.7 Do not eat <u>grapefruit</u> or drink grapefruit juice while using this drug .. <input type="checkbox"/> <input type="checkbox"/></p> <p>4.8 Should have <u>liver function tests</u> before and after starting this medicine and on regular basis to check for harmful effects. .... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>
<p><b>2. Contraindications and what to do if applicable.</b></p> <p>Do not take this medicine if you are:</p> <p>2.1 <u>allergic</u> to atorvastatin ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.2 <u>pregnant</u> or may become pregnant; can cause harm to baby ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.3 <u>nursing</u> or breast-feeding ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if you:</p> <p>2.4 drink large amounts of alcohol ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.5 have had liver disease ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.6 have had kidney disease ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.7 have had recent major surgery ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.8 have uncontrolled seizures ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>5. Symptoms of serious or frequent adverse reactions and what to do</b></p> <p>Tell PR or PH as soon as possible if any of these occur:</p> <p>5.1 muscle pains or weakness, especially with fever ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.2 unusual tiredness ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.3 dark urine or yellowing of skin or eyes ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.4 skin rash ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if these do not go away or bother you:</p> <p>5.5 constipation ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.6 diarrhea ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.7 headache ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.8 nausea or heartburn ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>
<p><b>3. Specific directions about how to use, monitor, and get most benefit</b></p> <p>3.1 It is important to take this medicine <u>regularly</u> to get the most benefit . <input type="checkbox"/> <input type="checkbox"/></p> <p>3.2 To help you remember, take it at the <u>same time(s)</u> each day ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>3.3 May take with or without <u>food</u> ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>3.4 If you <u>miss a dose</u>, take it as soon as possible <input type="checkbox"/> <input type="checkbox"/></p> <p>3.5 Skip missed dose if next scheduled dose is less than 8 hours away ... <input type="checkbox"/> <input type="checkbox"/></p> <p>3.6 Do not take two doses at the same time (or: double up) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>3.7 <u>Cholesterol levels</u> should be monitored on a regular basis ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>3.8 Important to continue <u>proper diet and exercise</u> ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>3.9 <u>Store</u> at room temperature, away from excess heat and moisture ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>6. General information and encouragement to ask questions</b></p> <p>6.1 Keep all medicines <u>away from children</u> ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>6.2 Do not give this medicine to <u>others</u> ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>6.3 Leaflet states that it does <u>not include all</u> uses, precautions, interactions, adverse reactions, or side effects ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>6.4 Name of <u>publisher</u> ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>6.5 <u>Date</u> of publication or most recent revision ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>6.6 Ask PR or PH <u>if any questions</u> or concerns ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>6.7 You may ask PH for <u>longer leaflet</u> written for professionals ..... <input type="checkbox"/> <input type="checkbox"/></p> <p style="text-align: center;">*****GO TO PAGE 2*****</p> <p>Comment:</p>

Criterion 7: Information is scientifically accurate, unbiased, up-to-date	Criterion 8: Information is readily comprehensible and legible.
<p>7.1 information is neutral in content and tone . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.2 no unapproved uses are listed (see 1.0 for approved uses) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.3 no promotional messages about a specific brand, manufacturer, or distributor (may compare chemical entities) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.4 no inaccurate or outdated claims about benefits of product . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.5 no inaccurate or outdated claims about risks of product . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>7.6 no other inaccurate or outdated information was found by this rater . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>NOTE: All items should be completed even if no information is provided about the uses, benefits, or risks of a product. The purpose is to identify inaccurate, biased, and/or outdated information</p> <p>Comment:</p>	<p>8.1 black box warning information printed in bold-face type or box . . . . . NA #</p> <p>8.2 minimal use of italics or ornate typefaces that are hard to read . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.3 upper and lower case lettering . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.4 headings placed on separate lines (not on same line as text) . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.5 bullets used to enhance readability . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>8.6 information is well organized and easy to find . . . . . <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p> <p><u>The following will be assessed by office staff – leave boxes blank</u></p> <p>8.7 adequate space between lines (<math>\geq 2.2</math> mm; this is approx. 2.2mm) . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.8 used no smaller than 10-point type (this is 10-point) . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.9 good ink-paper contrast . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p>8.10 written at 6-8th grade level (excluding drug names) . . . . . <input type="checkbox"/> <input type="checkbox"/> *</p> <p># none applicable for this drug * will be assessed by office staff, leave blank</p>

**Appendix C4: Patient Information Evaluation Form – NITROGLYCERIN (SUBLINGUAL)**

Office Use: Pharmacy ID: \_\_\_ Rater ID: \_\_\_ Leaflet ID: \_\_\_

**Rater:** Check two boxes  if sub-criterion is fully or nearly fully met. Other wording may be counted if it is equivalent or similar in meaning.  
 Check one box  if sub-criterion is partially met. Leave both boxes blank if no information is provided. PR= doctor or other prescriber; PH= pharmacist

<b>Criteria 1-6: Information is sufficiently specific and comprehensive.</b>	
<p><b>1. Drug names and indications for use</b></p> <p>1.1 generic name: nitroglycerin ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.2 phonetic spelling of generic name ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.3 common brand names: Nitrostat, NitroQuick, or Nitrotab ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.4 drug class: nitrates ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>1.5 used to relieve or prevent symptoms of angina (chest pain) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>4. Specific precautions and how to avoid harm while using it</b></p> <p>4.1 If possible, <u>sit down when using</u> this medicine. This may prevent falls due to dizziness ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.2 May cause dizziness when standing up or getting out of bed; <u>getting up slowly</u> may help ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.3 If become dizzy while sitting, take several deep breaths and bend forward with your <u>head between your knees</u> ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.4 Dizziness may be more frequent if you have had <u>alcohol</u>. Limit amount of alcohol while using this medicine ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.5 Tell PR or PH about any <u>other medications</u>, especially: ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.6 high blood pressure medicines ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.7 other heart medicines ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>4.8 sildenafil (Viagra); death can occur with combined use ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>
<p><b>2. Contraindications and what to do if applicable</b></p> <p>Do not take this medicine if you:</p> <p>2.1 are <u>allergic</u> to nitroglycerin or other nitrates ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if you:</p> <p>2.2 have other heart problems ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.3 have severe anemia ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.4 have recent stroke or head injury ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.5 have kidney disease ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.6 have liver disease ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.7 are <u>pregnant</u> or may become pregnant ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>2.8 are <u>nursing</u> or breast-feeding ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>	<p><b>5. Symptoms of serious or frequent adverse reactions and what to do</b></p> <p>Tell PR or PH as soon as possible if any of these occur:</p> <p>5.1 bluish lips or finger nails ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.2 blurred vision ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.3 drying of the mouth ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.4 severe headache ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.5 shortness of breath, weakness, or fainting [list 1] ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Tell PR or PH if any of these do not go away or bother you:</p> <p>5.6 feeling dizzy or lightheaded ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.7 fast pulse (or heartbeat) ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.8 flushing of face and neck ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>5.9 nausea or vomiting ..... <input type="checkbox"/> <input type="checkbox"/></p> <p>Comment:</p>

**Criteria 1-6: Information is sufficiently specific and comprehensive.**

**3. Specific directions about how to use, monitor, and get most benefit**

- 3.1 Use one tablet at first sign of angina attack (chest pain) .....
- 3.2 Put tablet under tongue and let it dissolve .....
- 3.3 Do not chew, crush, or swallow it .....
- 3.4 This usually brings relief in 1 to 5 minutes .....
- 3.5 If no relief after 5 minutes, use a second tablet. If no relief after another 5 minutes, use a third tablet .....
- 3.6 If no relief after three tablets in 15 minute period, call doctor and have someone take you to hospital emergency room .....
- 3.7 May use one tablet 5 to 10 minutes before an expected attack .....
- 3.8 Store in original glass screw-cap bottle, tightly capped .....
- 3.9 Store at room temperature, away from excess heat and moisture .....

Comment:

**6. General information and encouragement to ask questions**

- 6.1 Keep all medicines away from children .....
- 6.2 Do not give this medicine to others .....
- 6.4 Leaflet states that it does not include all uses, precautions, interactions, adverse reactions, or side effects .....
- 6.5 Name of publisher .....
- 6.6 Date of publication or most recent revision .....
- 6.7 Ask PR or PH if any questions or concerns .....
- 6.8 You may ask PH for longer leaflet written for professionals .....

\*\*\*\*\*GO TO PAGE 2\*\*\*\*\*

Comment

**Criteria 7: Information is scientifically accurate, unbiased, up-to-date**

- 7.1 information is neutral in content and tone .....
- 7.2 no unapproved uses are listed (see 1.0 for approved uses) .....
- 7.3 no promotional messages about a specific brand, manufacturer, or distributor (may compare chemical entities) .....
- 7.4 no inaccurate or outdated claims about benefits of product .....
- 7.5 no inaccurate or outdated claims about risks of product .....
- 7.6 no other inaccurate or outdated information was found by this rater ..

NOTE: All items should be completed even if no information is provided about the uses, benefits, or risks of a product. The purpose is to identify inaccurate, biased, and/or outdated information

Comment:

**Criterion 8: Information is readily comprehensible and legible.**

- 8.1 black box warning information printed in bold-face type or box ..... NA #
- 8.2 minimal use of italics or ornate typefaces that are hard to read .....
- 8.3 upper and lower case lettering .....
- 8.4 headings placed on separate lines (not on same line as text) .....
- 8.5 bullets used to enhance readability .....
- 8.6 information is well organized and easy to find .....

Comment:

The following will be assessed by office staff – leave boxes blank

- 8.7 adequate space between lines ( $\geq 2.2$  mm; this is approx. 2.2mm) ....   \*
- 8.8 used no smaller than 10-point type (this is 10-point) .....   \*
- 8.9 good ink-paper contrast .....   \*
- 8.10 written at 6-8th grade level (excluding drug names) .....   \*

# none applicable for this drug

\* will be assessed by office staff, leave blank

## Appendix D: Readability Assessment Procedures

1. Count off 100 words in succession (W), beginning with paragraph on how to use or take the medicine. Mark the beginning and the end of 100 word sample with brackets [ ]. If leaflet is shorter than 100 words, begin with first instructional or informational statement. Do not count patient or provider names or label directions. Count hyphenated words as a word. Count Roman or Arabic numbers as words. Abbreviated words also are counted as words.
2. Mark the end of each sentence with a check (✓). Count the number of sentences (S). If the 100-word mark falls past the middle of a sentence, include this sentence in the count. A sentence includes any grammatically independent unit ending with a period (.), question mark (?), exclamation point (!), semicolon (;), or colon (:).
3. Underline or circle all words having three or more syllables (T). Count the number of words having three or more syllables, BUT DO NOT COUNT:
  - a) verbs ending in “ed” or “es” that make the word have a third syllable
  - b) drug names (brand or generic)
  - c) combinations of two simple words (e.g. “overdose”)
4. Write # words, # sentences, and # of three or more syllable words in pencil on the copy of information sheet. These data will be entered into the computer.
5. Use computer to calculate grade level using the Gunning Fog equation:

$$GL = (W/S + T) \times 0.4$$

where GL is grade level, W is number of words in the sample (usually 100), S is number of sentences in the sample, and T is the number of words having three or more syllables in the sample.

Reference: R. Gunning, *The Technique of Clear Writing*. Rev Ed. New York: McGraw–Hill, 1968, pp.38-39.

**Appendix E: Consumer Evaluation Form, 2001**

**Consumer ID:** \_\_\_\_  
**Sheet #:** \_\_\_\_\_

Thank you for reading and answering some questions about the attached patient information sheet. Only a few people are being asked to help evaluate this material so your opinions are important. All answers will be kept confidential.

1. Below is a list of words describing the attached information sheet. For each item, please **circle one number** that best describes how **YOU** would feel if you were taking this medicine for the first time and received this information sheet from the pharmacy.

poor print size	1	2	3	4	5	good print size
poor print quality	1	2	3	4	5	good print quality
poor spacing between lines	1	2	3	4	5	good spacing between lines
poorly organized	1	2	3	4	5	well organized
poor length	1	2	3	4	5	good length
unattractive	1	2	3	4	5	attractive*
unclear	1	2	3	4	5	clear
unhelpful	1	2	3	4	5	helpful
incomplete	1	2	3	4	5	complete
scary	1	2	3	4	5	reassuring*
hard to find important information	1	2	3	4	5	easy to find important information
hard to remember	1	2	3	4	5	easy to remember*

2. **Overall**, what is your opinion about this information sheet. Please **circle** one number that best describes how **you** would feel if you received this information sheet.

hard to read	1	2	3	4	5	easy to read
hard to understand	1	2	3	4	5	easy to understand
not useful	1	2	3	4	5	useful

3. Do you have any other comments about this information sheet? (Write on back of page if you wish)
- 

[\*Item not included in calculation of adherence score]