This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville, MD 20850

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Over the past few years the Food and Drug Administration (FDA) has required manufacturers of peak flow meters to include the prescription legend in new devices because of the claims made in their labeling. Since the National Institutes of Health (NIH) released a guidance for the treatment of asthma, which recommend patient monitoring with a peak flow meter, there has been an interest in making peak flow meters widely available. The attached Guidance for Labeling of Peak Flow Meters for Over the Counter Sale was developed by the National Heart, Lung, and Blood Institute (NHLBI) of NIH to facilitate the nonprescription use of these devices, and was distributed to the Anesthesiology and Respiratory Therapy Devices Panel of the FDA for their review. The Panel concurred with the NHLBI Guidance, agreed that it was reasonable to distribute these devices OTC if the labeling guidance is fulfilled, and provided some specific suggestions which are incorporated into the Guidance.

Consequently, we have determined that Peak Flow Meters, which meet the following criteria, shall be considered to bear adequate directions for use in conformance with section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act, and shall therefore not require the prescription legend specified in 21 CFR 801.109:

1. The device

   a. Only measures peak flow,

   b. Is not programmable,

   c. Does not require physician or other health care provider adjustment,

   d. Does not alert the patient to take medication; and

2. The labeling is in conformance with the Guidance for Labeling of Peak Flow Meters for Over the Counter Sale.

Peak Flow Meters, for which a Substantial Equivalence determination has been issued under the 510(k) process, and which meet the above criteria, may be relabeled for over-the-counter sale without the submission of a new 510(k). Any other changes to the device or labeling will require the submission of a new 510(k). Peak Flow Meters which do not meet the requirements above and do not contain in their labeling the prescription legend required under 21 CFR 801.109(b)(1) shall be considered to be misbranded. Please send a copy of your labeling to Michael S. Gluck (HFZ-450) at the letterhead address above.

If you have any questions regarding this letter you may contact Michael S. Gluck, D.Sc., P.E., at (301) 427-1053.

Sincerely yours,

for Abhijit Acharya, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

DIVISION OF CARDIOVASCULAR,
RESPIRATORY, AND NEUROLOGICAL DEVICES

GUIDANCE DOCUMENT

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Guidance for Labeling Peak Flow Meters for Over the Counter Sale	1.0

Version	Revision History	Date

Approved by:		Date
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TABLE OF CONTENTS

Subject	Page
1.0 Introduction	1
2.0 Outside Container or Wrapper Labeling Requirements	4
3.0 Package Insert Labeling Requirements	7
3.1 Intended Use	7
3.2 How the Peak Flow Meter Works	9
3.3 Contents of the Package	10
3.4 Warnings and Precautions	10
3.5 Instructions	12
3.5a Pre-instruction Statement	12
3.5b Step -by -Step Instructions	13
3.6 Results and Record of Results	14
3.7 Troubleshooting	17
3.8 Care of the Peak Flow Meter	18
3.9 Accuracy and Reliability	18
3.10 Warranty Information	19
3.11 Manufacturer	19
3.12 Date of Issuance	19
3.13 Label Changes	19
Appendix A: Summary Checklist	20

Version 1.0

DRAFT

Guidance for Labeling Peak Flow Meters for Over the Counter Sale

1.0 Introduction

Over the past few years the Food and Drug Administration (FDA) has required manufacturers of peak flow meters to include the prescription legend in new devices because of the claims made in the labeling and the lack of adequate directions for use. Since the National Institutes of Health (NIH) released a guidance for the treatment of asthma, which recommend patient monitoring with a peak flow meter, there has been an interest in making peak flow meters widely available. This guidance was developed by the National Heart, Lung, and Blood (NHLBI) Institute of NIH to facilitate the nonprescription use of these devices, and was distributed to the Anesthesiology and Respiratory Therapy Devices Panel of FDA for their review. The Panel concurred with the NHLBI Guidance, agreed that it was reasonable to distribute these devices over-the-counter (OTC) if the labeling guidance is fulfilled, and provided some specific suggestions which are incorporated into the guidance.

Consequently, the FDA has determined that Peak Flow Meters, which meet the following criteria, shall be considered to bear adequate directions for use in conformance with section 502(f)(1) of the Federal Food, Drug, and Cosmetic

Act, and shall therefore not require the prescription legend specified in 21 CFR 801.109:

1. The device
   a. Only measures peak flow,
   b. Is not programmable,
   c. Does not require physician or health care provider adjustment,
   d. Does not alert the patient to take medication; and

2. The labeling is consistent with this document.

Peak flow meters which do not meet all of the requirements above and do not contain in their labeling the prescription legend required under 21 CFR 801.109(b)(1) shall be considered to be misbranded. This guidance supplements, but does not take the place of the requirements of 21 Code of Federal Regulations (CFR) for each submission of a 510(k).

The information in this document should be included in the labeling of the peak flow meter, on the outside container and in the package insert. The information can be adapted in different formats. Examples are given to illustrate the concept. However, it is recommended that the text used by the manufacturers be written at a reading level no higher than the seventh grade, and be pretested with expected consumers. A summary checklist of the items in this document is provided in Appendix A; however, the content of the entire document must be considered when labeling the device.

Version 1.0

If you have any questions concerning this document, please contact Michael S. Gluck, D.Sc., P.E. at (310) 427-1053. A copy of this document may be obtained from the Division of Small Manufacturers Assistance (DSMA) at 800-638-2041 or (301) 443-6597.

2.0 OUTSIDE CONTAINER OR WRAPPER LABELING REQUIREMENTS

Within the limits of legal requirements, information should be provided that is important for the consumer to know before deciding whether to purchase the device. This information should include:

1) Name of the product

2) Lot number

3) Name and address of manufacturer

4) Brief description of intended use as a device for monitoring respiratory conditions such as asthma, including who would use it and conditions for its use. This section should include a statement that when the peak flow meter is used to monitor asthma, it is most useful to use it along with a treatment plan provided by the physician or other licensed health care professional. The section should also include a statement that keeping a written record of the peak flow measures is an important part of peak flow monitoring.

> For example: The peak flow meter is used to measure a person's "peak expiratory flow," which is the fastest speed a person can blow air out of the lungs after taking in as big a breath as possible. "Peak expiratory flow" is a simple measure of airflow in health and disease that can tell you how well you are breathing. It tells you how well air is moving through the airways in your lungs. If you have a breathing condition such as asthma, your physician or other licensed health care

professional may recommend that you use a peak flow meter to watch your asthma because it will help you find out if there are changes in your airflow. The physician or other licensed health care professional will give you a treatment plan that will tell you what actions to take when you have a change in airflow. In addition, a written record of your peak flow measures (see the "Peak Flow Diary" enclosed in the package) should be kept as recommended by your doctor or other licensed health care professional. Reviewing this diary can help you and your licensed health care professional check closely on your asthma to provide the best treatment for you.

Warnings and precautions. This lists precautions about following instructions and interpreting results. It should include a caution statement that when the peak flow meter is used to monitor asthma, the user should be under the supervision of a physician or other licensed health care professional. The section should also include a statement that the peak flow meter is intended for single person use and should not be used by more than one person. The warnings and precautions should be printed such that they stand out above all the other labeling.

For example: CAUTION: When the peak flow meter is used to watch a lung condition such as asthma, the user should be under the care of a physician or other licensed health professional. A licensed health care professional's advice is required to understand the meaning and

importance of the measures you get with your peak flow meter, and to help decide on an appropriate treatment plan.

Instructions for using the peak flow meter must be followed carefully in order to get a correct measure of airflow.

The peak flow meter should not be used by more than one person.

If you have any questions about your peak flow meter and its use, talk to your physician or other licensed health care professional.

3.0 PACKAGE INSERT LABELING REQUIREMENTS

The following statements should appear, in bold-faced capital letters or otherwise highlighted, on the front of the package insert, and/or on the package container or wrapper:

> **PLEASE READ ALL THE INFORMATION IN THE PACKAGE INSERT <u>BEFORE</u> USING THE PEAK FLOW METER.**
>
> **IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS, CONSULT ————————, CALL (800)————(specify days and times to call),OR WRITE TO ————.**

Provide space on the first page for the physician or other licensed health care professional to write in the patient's "good" flow rates and to provide specific interventions he/she recommends for ranges of decreased flow rates.

3.1) Intended Use

This should state the intended use of the device for monitoring respiratory conditions such as asthma and the rationale for its use, including who should use the device, the conditions for its use, and any contraindications. This section should elaborate on the use of peak flow meters at home for monitoring asthma. It should include a statement that when a peak flow meter is used to monitor asthma, it is most useful to use it along with a treatment plan

provided by the physician or other licensed health care professional. It should also include a statement that a written record of peak flow measures is an important part of the monitoring.

For example: The peak flow meter is used to measure a person's "peak expiratory flow," which is the fastest speed a person can blow air out of the lungs after taking in as big a breath as possible. "Peak expiratory flow" is a simple measure of airflow in health and disease that can tell you how well you are breathing. It tells you how well air is moving through the airways in your lungs. If you have a breathing condition such as asthma, your physician or other licensed health care professional may recommend that you use a peak flow meter to watch your asthma because it will help you find out if there are changes in your airflow. The physician or licensed health care professional will give you a treatment plan that will tell you what actions to take when you have a change in airflow. In addition, a written record of your peak flow measures (see the "Peak Flow Diary" enclosed in the package) should be kept as recommended by your physician or other licensed health care professional. Reviewing this diary can help you and your licensed health care professional check closely on your asthma to provide the best treatment for you.

3.2) How the peak flow meter works

This should present information, in lay terms, on the scientific basis of the test, what the test measures and what its results indicate. This includes information on when to test and how often the test should be used to monitor a condition such as asthma.

For example: The peak flow meter measures the "peak expiratory flow," which is the fastest speed a person can blow air out of the lungs after taking in as big a breath as possible. When you blow into the mouthpiece of the meter, an indicator moves along a scale with numbers on it. The faster you can blow into the meter, the higher the indicator will go on the peak flow meter. A peak flow measure with a high number usually means that air is moving easily through your lungs. When people with asthma have asthma episodes or attacks, their lungs are blocked and air cannot move easily. Therefore, the peak flow meter will help tell a person with asthma how much the lungs are blocked.

The peak flow number tells you how well air is moving through the airways in your lungs. When you use the peak flow meter regularly, you will be able to check for changes in your airflow. Changes in your airflow may require special treatment according to a treatment plan given to you by your physician or other licensed health care professional.

Your physician or other licensed health care professional will tell you when and how often to use the peak flow meter. It is generally recommended to use it two times a day, in the morning when you wake up and before you go to bed. The peak flow meter should also be used when you are feeling symptoms of breathing problems, in order to let you and your physician or other licensed health care professional know how serious the breathing problem is and how well your asthma treatment is working.

3.3) Contents of the package

All components of the kit and the function of each component should be explained. Illustrations of each component should be provided.

For example: the peak meter, with the mouthpiece, scale, and indicator labeled; a diary card; the peak flow norms if enclosed.

3.4) Warnings and Precautions

Appropriate warnings and precautions should be expressed in lay terms. This section should list precautions about following instructions and interpreting results. It should include a caution statement that when the peak flow meter is used to monitor asthma, the user should be under the supervision of a physician or other licensed health care professional. The section should also include a statement that the peak flow meter should not be used by more than

one person. The warnings and precautions should be printed such that they stand out above all the other labeling.

For example: CAUTION: When the peak flow meter is used to watch lung conditions such as asthma, the user should be under the care of a physician or other licensed health care professional. A licensed health care professional's advice is required to understand the meaning and importance of the measures you get with your peak flow meter, and to decide on an appropriate treatment plan.

The treatment plan given to you by your physician or other licensed health care professional will tell you what action to take when there are changes in your peak flow number.

No matter what your peak flow measures are, if you have signs and symptoms such as chest tightness, shortness of breath, coughing or wheezing you should follow your licensed health care professional's advice for contacting him or her.

Instructions for using the peak flow meter must be followed carefully in order to get a correct measure of airflow.

If you are unable to obtain a reading you should contact your physician immediately.

The peak flow meter should not be used by more than one person.

If you have any questions about your peak flow meter and its use, talk to your licensed health care professional.

3.5) Instruction

3.5a) Pre-instruction statement

The following statements should be repeated before the step - by -step instructions are given.

PLEASE READ ALL THE INFORMATION IN THE PACKAGE INSERT BEFORE USING THE PEAK FLOW METER.

IF YOU DO NOT UNDERSTAND THE INSTRUCTIONS, CONSULT ————————, CALL (800)————(specify days and times to call),OR WRITE TO ————————.

ASK YOUR PHYSICIAN OR OTHER LICENSED HEALTH CARE PROFESSIONAL TO WATCH YOU USE THE PEAK FLOW METER. THIS WILL HELP ASSURE THAT YOU ARE USING IT CORRECTLY.

NO MATTER WHAT YOUR PEAK FLOW MEASURES ARE, IF YOU HAVE SIGNS AND SYMPTOMS SUCH AS CHEST TIGHTNESS, SHORTNESS OF BREATH, COUGHING OR

WHEEZING YOU SHOULD FOLLOW YOUR LICENSED HEALTH CARE PROFESSIONAL'S ADVICE FOR CONTACTING HIM OR HER.

IF YOU ARE UNABLE TO OBTAIN A READING YOU SHOULD CONTACT YOUR PHYSICIAN IMMEDIATELY.

3.5b) Step -by -step Instructions

This section should give explicit steps for taking a peak flow measurement. Pictorial representation of each step would be beneficial. However, illustrations of the correction position of the mouth on the mouthpiece, and at least two sample peak flow readings showing the indicator on the peak flow meter scale (clearly marked "sample only") are essential.

For example:

- Get the peak flow meter ready (take out of case, insert mouthpiece, position indicator; directions will differ according to device)
- Stand up
- Take a deep breath in
- Place the meter in the mouth and close lips around the mouthpiece. Make sure your lips form a tight seal around the mouthpiece. Do not put your tongue into the mouthpiece. Do not bend your neck.
- Blow out as hard and fast as you can.

- Read the number next to the indicator. This is your peak flow measure. Write it down.
- After you move the indicator back to zero, repeat the steps two more times to get two more peak flow measures.
- Choose the highest number of your three peak flow measures. Write the number in your " Peak Flow Diary." Directions for the diary are written on the diary.
- How to store your peak flow meter (directions will differ according to device).

3.6) Results and Record of Results

This section explains how test results are read, recorded, and used. Reference to a record keeping "diary" and instructions for using the diary should be included. This section also explains the meaning of possible test outcomes, with an emphasis on monitoring changes in an individual's airflow for people with lung conditions such as asthma. A table of standardized peak flow norms showing the significance of a particular peak flow value or range of values should be included. The standardized norms that are used should be appropriately referenced from the medical literature. The table and this section of the package insert should include a note about limitations of using standardized peak flow norms, along with a recommendation for a consultation with the physician or other licensed health care professional in order to obtain the best peak flow standard for the individual. A caution about interpreting results should be included on the table and in this section.

This caution should explain that when a person uses the peak flow meter to monitor asthma, a physician or other licensed health care professional should be contacted, according to the treatment plan recommended by the licensed health care professional, when there is a change in peak flow measures or if the person experiences asthma symptoms regardless of the peak flow measure. It should also be recommended to record, at the beginning of the peak flow diary, the flow rates that are good, and the specific interventions recommended by the physician or other licensed health care professional for lower flow rates.

For example: Peak flow measures are used to follow breathing conditions such as asthma. Taking peak flow measures every day and keeping a record of the peak flow measures in your "Peak Flow Diary" can help you and your physician or other licensed health care professional make important decisions about your treatment. See the "Peak Flow Diary" for specific instructions on keeping a record of your peak flow measures.

If you use the peak flow meter to watch asthma, a peak flow measure with a low peak flow number or a reduction in peak flow numbers from one measuring time to the next may mean that your asthma is getting worse. This means that you and your physician or other licensed health care professional may need to take action. CAUTION: The treatment plan given to you by your physician or other licensed health care professional will tell you what action to take when there are changes in your peak flow number. No matter what your peak flow measures are, if you have signs

and symptoms such as chest tightness, shortness of breath, coughing or wheezing you should follow your licensed health care professional's advice for contacting him or her.

A peak flow measure with a high peak flow number usually means that your airflow is good. To get a general idea if your peak flow number is high enough for you, you can compare your peak flow number with the numbers of other people your sex, age, and height. The table "Peak Flow Norms" (or whatever label the individual manufacturer uses) in this package shows the peak flow numbers that are generally predicted, or expected, for people who have different ages and heights. But it is important to know that these predicted peak flow norms are average numbers for large groups of people. You may have a higher peak flow number than the average number for a large group and you may not be healthy. Or you may have a lower peak flow number than the average number for a large group and you may be healthy. The best way to determine what is a healthy peak flow number for <u>you</u> is to discuss this with your physician or other licensed health care provider. It is important to watch for <u>changes</u> in your peak flow number from one measuring time to the next and to discuss these changes with your physician or other health care professional according to your treatment plan.

3.7) Troubleshooting

This section presents possible explanations and corrective actions to be taken for unexpected results. A telephone number (toll free is preferred) should be available for more direct consumer support. A description of how to recognized malfunction of the device should be included.

For example: If your peak flow measure gives you a peak flow number that is low and this surprises you because you are feeling fine or because you have never before had such a low measure, this could mean different things. It could mean that peak flow meter is broken. Or it could mean that you did not follow directions correctly. If you are using the peak flow meter to watch a breathing condition such as asthma, a surprisingly low peak flow measure could be an early warning that your asthma is getting worse, because a low peak flow measure can occur before any signs or symptoms are felt.

If the meter is broken, the indicator will not move when you blow into the mouthpiece. (Add here any other information specific to the device that lets the consumer know if the peak flow meter is broken.)

If you do not follow all instructions for taking a peak flow measure carefully, you may get an inaccurate result. An accurate peak flow measure depends entirely on you following all of the steps! If your

peak flow number is low and this surprises you, read the instructions again and follow them carefully.

If you have any questions about whether your peak flow meter is working correctly, call --------

3.8) Care of the Peak Flow Meter

This section describes how to care for and clean the peak flow meter. It should also indicate how often the peak flow meter should be cleaned. Any known adverse conditions (i.e. excess heat, cold, altitude, etc.) that may affect functioning of the peak flow meter should be described. Directions will depend on the device, so no example is given.

3.9) Accuracy and Reliability

This section includes a brief statement about whether the peak flow meter meets standards established by an independent organization.

For example: This product and its accompanying literature meet National Institute of Health, National Heart, Lung, and Blood Institute recommendations for peak flow meters, (Division of Lung Diseases,

National Heart, Lung, and Blood Institute, National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services: "Statement on Technical Standards for Peak Flow Meters," NIH Publication No. 92-2113a, October 1992).

3.10) Warranty Information

This section describes any warranty that is offered by the manufacturer.

3.11) Manufacturer

.st the name and address of the manufacturer or distributor and a way to reach the customer service department.

3.12) Date of Issuance/ Lot number

The date of the latest revision to the device should also be noted.

3.13) Label Changes

Highlight any significant changes that have occurred that may affect proper use of the device, especially in cases where users may assume the same procedure is to be followed unless alerted to modifications.

Appendix A

SUMMARY CHECKLIST: Guidance for Labeling Peak Flow Meters for Over the Counter Sale

The following list summarizes the topics that should be included about the peak flow meter on the outside container or wrapper, and in the package insert.

1. Outside Container or Wrapper

   a. Name of product

   b. Lot Number

   c. Name and address of manufacturer

   d. Brief description of intended use as a device for monitoring respiratory conditions such as asthma.

   e. Warnings and precautions, including a statement that when the peak flow meter is used to monitor asthma, the user should be under the supervision of a physician or other licensed health professional. The section should also include a statement that the peak flow meter is intended for single person use unless washed thoroughly after each use or unless multiple mouthpieces are provided.

2. Package Insert

   a. Warning to read all instructions, and number to call if instructions are not understood

   b. Intended use as a device for monitoring respiratory conditions such as asthma.

   c. How the peak flow meter works

   d. Contents of the package

   e. Warnings and precautions, including a statement that when the peak flow meter is used to monitor asthma, the user should be under the supervision of a physician or other licensed health care professional. This section should also include a statement that the peak flow meter is intended for single person use unless it is cleaned thoroughly after each use or multiple mouth pieces are provided.

   f. Instruction on use, with illustrations

g. Warning to read all instructions, and to have the licensed health care professional observe use.

h. Step by step instructions.

i. Results and record of results, including:

- A caution that if the peak flow meter is used to monitor asthma, a physician or other licensed health care professional should be contacted, according to the treatment plan recommended by the licensed health care professional, when there is a change in peak flow readings or if the person experiences asthma symptoms regardless of the peak flow reading.

- Reference to an enclosed diary and instructions for using the diary

- A table of standardized peak flow norms, with a discussion of the limitations of using standardized norms on the table as well as in this section.

- Emphasize the importance of change and the need for the physician or other licensed health care professional to define the amount of change requiring various interventions.

j. Troubleshooting, including how to recognize malfunction of the device.

k. Care of the peak flow meter.

l. Accuracy and reliability, including statement on meeting recommended standards.

m. Warranty information.

n. Manufacturer.

o. Date of Issuance.

p. Label changes.

II. TECHNICAL REQUIREMENTS FOR PEAK FLOW METERS**

1. A peak flow meter must be accurate over its full range (100 to 400 liter/minute for children and from 100 to 700 liter/minute for adults) within plus or minus 10% of the readings. The accuracy and reproducibility should be verified by the manufacturer using the waveforms shown in the table below. Waveform 24 from the American Thoracic Society Standard Test Waveform Set[1] and peak flow variants on this waveform should be generated with a pump[2] to test and validate the accuracy of a particular peak flow measuring device and to assess inter-device comparability.

2. The devices should have good reproducibility, within 10 liters per minute or ± 5% of reading, whichever is larger, so that small changes in PEFR can be detected.

3. Inter-device variability should be small (within ± 5%).

4. Data on device life span and evidence of durability should be presented.

Waveforms and Their Target Peak Flow for ATS Waveform 24

Target Flow Value (Liters/Minute)	Waveform 24 Multiplier
100.56	0.80
125.70	1.00
150.84	1.20
201.12	1.60
251.40	2.00
301.68	2.40
351.96	2.80
502.80	4.00
716.49	5.71

There are 24 waveforms in the American Thoracic Society (ATS) Standard Test Waveform Set. Waveform 24 was chosen as the standard waveform to be used for testing peak flow meters. Several of the ATS waveforms have problems such as inadequate start of test, double flow peaks, and other artifacts which were designed to test spirometers. These problems make use of several of the waveforms inappropriate for testing the reproducibility of peak flow meters. In addition, ATS waveform 24 allows the testing of peak flow meter reproducibility over a large range of peak flows. ATS waveform 24 was chosen since it has a relatively normal shaped flow-volume and its peak flow can be increased or decreased by adjusting multiplying factors as noted above.

** Manufacturers are encouraged to develop special features that will also meet the needs of the handicapped.