FOOD AND DRUGS AUTHORITY

GUIDELINES FOR THE REGISTRATION OF HOMEMADE FACE MASKS

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1.0 INTRODUCTION

The Food and Drugs Authority (FDA) plays a critical role in safeguarding/protecting the health and safety of Ghana and its citizens. The FDA is therefore committed to providing timely guidance and policies to support the Government of Ghana's response efforts during public health emergencies such as the Coronavirus Disease (COVID-19) pandemic.

This Guideline outlines information and recommendations by the FDA to help expand the availability and accessibility of homemade face masks for use by the general public. The guideline thus provides information on the production of homemade face masks from local fabrics, safe and proper use as well as the cleaning of same.

In executing its mandate, the FDA takes cognizance of the powers granted the Minister of Health by Sections 169 – 173 of the Public Health Act, 2012 (Act 851) in the event of a public health emergency and provides this Guidance to also help reduce the pressure on clinical (medical grade) face masks such as surgical and N95 face masks which are in global shortage and must be reserved for frontline health care workers.

2.0 BACKGROUND

The Coronavirus Disease (COVID-19) is caused by a coronavirus called SARS-CoV-2 which is thought to be transmitted from person to person, mainly through respiratory droplets from an infected person directly to uninfected persons or through contact with contaminated surfaces or object (fomite).

These droplets either land on the mouths, noses or eyes of uninfected persons interacting in close proximity (within about 2 metres) or fomites which get picked up by uninfected persons, hence the recommendation for the practice of frequent hand washing hands with soap under running water or using an alcohol-based hand rub.

During the initial onset of the disease, both the World Health Organisation (WHO) and the United States Centers for Disease Control and Prevention (CDC) recommended that only frontline health workers and infected persons with the COVID-19 should wear face masks.

However, recent studies have shown that many individuals with COVID-19 are asymptomatic (without symptoms) or pre-symptomatic (develop symptoms later) and can infect others before exhibiting symptoms. Thus, the virus may be spread by infected people who may not be showing symptoms and are in close engagements with uninfected persons via speaking, coughing or sneezing.

Due to the findings and coupled with the surge in community spread of the COVID-19 in many affected geographic areas, the CDC now recommends that people in the United

States of America (U.S.A) wear cloth face coverings (homemade face masks) in public places where social distancing protocols are difficult to observe.

Across the world, a number of Countries are enforcing compulsory wearing of face masks by the general public as one of the measures to help limit the spread of the virus especially in hotspot communities and public areas of significant community-based transmission. These countries include but are not limited to China, Hong Kong, South Korea, Japan, Thailand and Taiwan in Asia, Slovakia, Bosnia-Herzegovina, Czech Republic, Austria in Europe as well as Morocco in Africa.

It is important to note that in all the listed jurisdictions, the cloth face coverings or homemade face masks made from household items or from common local materials/fabrics are not substitutes for social distancing. Hand hygiene combined with maintaining social distancing remains a critical means of fighting COVID-19 within communities.

The use of homemade face masks, however, help to slow the spread of the virus and can prevent people who may have the virus but do not know it from infecting other persons. The masks limit the spread of the virus from the mask wearer to other persons by blocking large droplets from coughing, sneezing or talking.

With Ghana experiencing a dwindling supply of PPEs as is the case globally, the Government of Ghana has engaged local manufacturing companies to assist in the domestic production of PPEs and has thus earmarked on the production of 3,600,000 face masks from local fabrics/materials to help protect the general public from COVID-19.

Several individuals, households and other private sector organisations have also started local production of homemade face masks to offer self-protection especially in public places. There is therefore a need for general information and guidelines to ensure proper and safe use and/or handling of these face masks. This policy will help to foster the availability of homemade face masks which may offer some health benefits to the general public during the COVID-19 pandemic.

The FDA has developed specifications for the production of homemade face masks and has also established an evaluation protocol for the materials used to produce same. Investigations on other types of homemade PPEs are on-going to inform recommendations on their proper use in Ghana. This Guidance will be in effect only for the period of the public health emergency in relation to the COVID-19 outbreak.

In the development of this guidelines, reference was made to the CDC, WHO, Project Protect (University of Utah Health, Latter-day Saint Charities and Intermountain Healthcare) and USFDA’s guidelines on cloth face coverings/masks.

3.0 DEFINITIONS

For the purposes of these Guidelines, unless the context otherwise requires, the following terms have the assigned meanings:

Medical Grade Face Mask: A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It is made from medical grade polypropylene while following fabrication guidelines.

Homemade Face Mask: A locally made face mask fashioned from breathable local cloth, fabric or material which may protect the user and those in close proximity from large respiratory droplets from coughs, sneezes or talking.

Surgical Mask: A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate material. The mask meets certain fluid barrier protection standards and class I or class II flammability tests.

N95 Respirator: A disposable half-mask filtering facepiece respirator (FFR) that covers the user's nose and mouth, and offers protection from particulate materials at an N95 filtration efficiency level. This class II device is mainly used in a healthcare setting.

Filtering Facepiece Respirator: A filtering face piece respirator is a disposable non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the user to help reduce user exposure to pathogenic biological airborne particulates.

Calico: Local cotton material used to make homemade face mask

ACRONYMS

FDA: Food and Drugs Authority

USFDA: United State of America's Food & Drugs Administration

CDC: Centers for Disease Control and Prevention

WHO*:* World Health Organization

PPE: Personnel Protective Equipment

COVID-19: Coronavirus Disease 2019

SARS-CoV-2: Severe Acute Respiratory Syndrome Coronavirus 2

FFR: Filtering Facepiece Respirator

4.0 PURPOSE

This policy provides guidance and recommendations on the production, proper and safe use and/or handling of homemade face masks. It is aimed at fostering the availability of face masks to individual homes in order to offer some health benefits to the general public during the COVID-19 outbreak. The recommendations stipulated in these guidelines will be updated as and when additional information becomes available.

5.0 SCOPE

This policy applies to all homemade face masks produced locally from local cloth, fabric or materials to provide some protection to individual and households during the COVID-19 outbreak.

This is in accordance with Section 148 of the Public Health Act, 2012, Act 851.

6.0 GENERAL GUIDELINES/RECOMMENDATIONS FOR HOMEMADE FACE MASKS

New evidence from research shows that infected people without symptoms can infect others in close proximity when they cough, sneeze or speak. Using simple and easy-to-make homemade face masks will help people who may have the virus without knowing it from transmitting it to others.

Wearing these homemade face masks in public places such as supermarkets, lorry stations, markets, shopping malls, bus terminals, pharmacies etc where social distancing measures are difficult to maintain especially in areas or communities identified as hotspots of the virus is therefore recommended.

Homemade face masks are however not recommended for people with difficulty in breathing or unconscious, incapacitated or otherwise unable to remove the mask without assistance including young children under the age of 2 years.

It is strongly recommended that whether using these masks or not, frequent hand washing, practicing social distancing (2 metres) as well as avoiding touching of face should be adhered to in order to limit the spread of COVID-19.

7.0 SPECIFIC RECOMMENDATIONS FOR HOMEMADE FACE MASKS

7.1 Fabric and Design

There is no standard design for a homemade face mask. Innovation is therefore encouraged together with the following recommendations:

- The fabric or material used for homemade face masks should be clean and free from all chemicals.

- In the event that printed fabric or material is used, the layer of the fabric in direct contact with the face (inner layer) should be plain fabric and free from any form of chemicals.

7.2 Fabric/Material Combinations

To be effective, face masks generally must be able to filter out particles and still be easy to breathe through. In the absence of propylene, which is the common material used for medical grade face masks, 100% cotton or cotton blends possess good material characteristics for homemade face masks. Recent studies/evaluations undertaken by the FDA on viable materials for the production of effective homemade face masks from local fabrics/materials established the following:

1. Calico-Stiff (Hard/Medium)-Calico (three layers) combination is ideal for reusable homemade COVID-19 face mask.
2. Calico-Calico-Calico (three layers) combination is ideal for reusable homemade COVID-19 face mask.
3. Calico-Paper Fibre-Calico (three layers) is suitable only for single-use homemade COVID 19 face mask.
4. Paper-Paper-Paper (three layers) combination is NOT suitable and, therefore, not recommended for use as COVID-19 face mask.

7.3 Handling (Wear & Use) of Homemade Face Masks

For homemade face masks to be effective, they must be designed to incorporate the following minimum qualities:

1. Fit tightly but comfortably against the side of the face
2. Cover your nose and mouth adequately and be secured with ear loops or ties so that no gaps occur when talking or moving.
3. Include multiple layers of fabric but allow breathing without restriction
4. Be easily washed, dried and be able to handle high temperatures and bleach without damage or deforming

Putting on a Face Mask

1. Ensure you are using a clean face mask
2. Wash hands with soap and water or alcohol-based hand sanitizer before touching face mask
3. Pick up face mask by touching ear loops only and not the mask itself
4. Hold both ear loops and place a loop around each ear.
5. Fit mask around mouth, nose, and chin

While Wearing a Face Mask

1. Face mask should be either completely on or off; not rest it under chin.

2. Never wear face mask inside-out.
3. Remove face mask if soiled or damp; do not reuse a single-use mask
4. Do not touch the face mask, your face, or adjust mask while it is on.
5. If you touch the mask, wash hands with soap and water or hand sanitizer immediately.

Removing a Face Mask

1. Grab ear loops only and lift the mask off ears.
2. Pull bottom of mask off and away from mouth and chin.
3. For mask to be reused immediately, place in a clean paper bag in order not contaminate other surfaces.
4. If it is a single-use mask, discard it directly into the garbage.
5. Clean hands with soap and water or alcohol-based hand sanitizer

7.4 Cleaning of Face Masks

Reusable homemade face masks should be properly cleaned or washed before reuse. Used homemade face masks must first be disinfected; then washed with soap or detergent until clean, rinsed under running water, dry in the open sun and ironed before reuse. They should be routinely washed depending on the frequency of use or when saturated from condensation build up from breathing, or after a contamination event.

Alternatively, homemade face masks may be washed (laundered) in hot water (about 70^0C) with soap or detergent, rinsed with clean water and allowed to dry in open sun.

Homemade face masks may be disinfected by soaking them for 5 minutes in a solution of 10ml (2 tablespoon) of bleach per litre of clean water.

7.5 Frequently Asked Questions

- **Why does one need to wear a homemade face mask?**
  Recent studies have shown that infected people without symptoms can transmit the disease to other close persons through droplets from talking, sneeze etc. Wearing homemade face mask can help protect people around users if they are infected but do not have symptoms or are not aware.

- **Do homemade face masks protect against COVID-19?**
  Homemade face masks can offer protection against COVID-19 as they help to block large respiratory droplets from coughing, sneezing and talking discharged from the face mask user to others. Thus, helping to slow the spread of the disease.

- **Should people observe social distancing while wearing homemade face mask?**
  Yes. Wearing homemade face masks is an additional public health measure and not a substitute for social distancing. Therefore, when combined with social distancing, frequent hand washing and proper mask use, homemade face masks may help to slow the spread of COVID-19 in Ghanaian communities.

- **Is there a standard design for homemade face masks?**
  There is no standard design for a homemade face mask therefore, consider innovation while following the recommendations under section 7.2 of these guidelines.

- **Are some people exempt from homemade face masks?**
  Yes. Homemade face masks are not recommended for children 2 years old and below, persons with trouble breathing, unconscious, incapacitated or otherwise unable to remove the face mask without assistance.

- **Why are people being encouraged to wear homemade face masks instead of clinical or medical grade face masks?**
  The COVID-19 pandemic has resulted in an increased demand for medical grade face masks globally. Consequently, these face masks such as surgical masks and N95 respirators are in short supply and must be reserved for frontline healthcare workers who need them most.

8.0 REGISTRATION REQUIREMENTS

8.1 Documentation

- Covering Letter
- Complete the Application Form for Class I Medical Devices (available online at the FDA website - www.fdaghana.gov.gh)

8.2 Fee

- Application Fee - GHC 750
- Manufacturing Premises Licensing Fee - GHC 100

8.3 Specifications

i. Dimension
   - Length: Cheek-to-cheek: 25.40cm
   - Width: 15.24cm
   - Thickness: Three layers- Not less than (NLT) 0.759mm

ii. Porosity: NLT 10000 Pascal

iii. Splash Test (Alcohol-based aerosol spray): No stain of alcohol-based aerosol should be seen at the reverse side of the face mask.

iv. Filtration of Bacteria: Reduction of NLT 3 log

8.4 Samples

Twelve (12) samples or pieces of homemade face masks shall be submitted.

8.5 Labeling

Company identification tags shall be provided on homemade face masks, including FDA Registration Number.

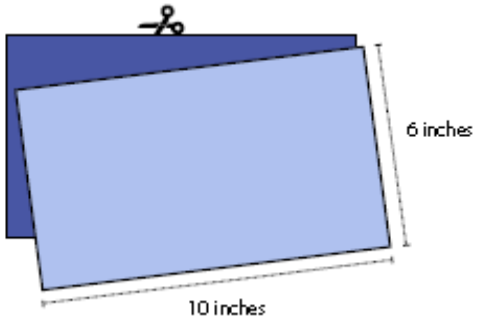
9.0 GUIDE FOR ASSEMBLING/MAKING FACE MASK

9.1 Materials

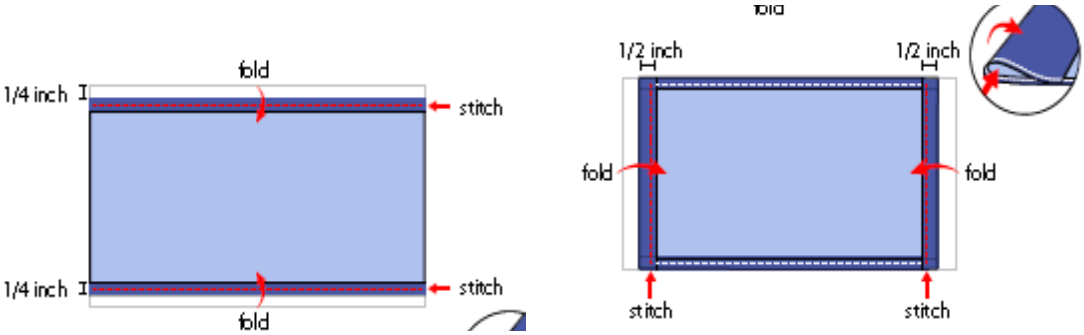
i. Two 10”-by-6” (25.40cm x 15.24cm) rectangles of cotton fabric (calico)
ii. Two 6” (15.24cm) pieces of elastic (or rubber bands, string, cloth strips, or hair ties)
iii. Needle and thread (or bobby pin)
iv. Scissors
v. Sewing machine

9.2 Assembly Guide

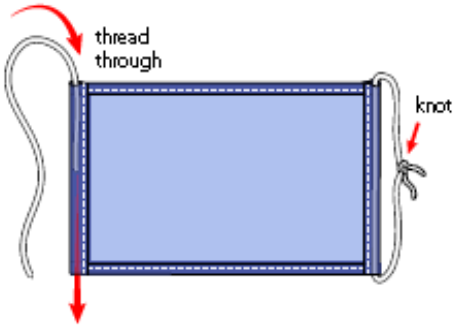
1. Cut out two 10”-by-6” (25.40cm x 15.24cm) rectangles of cotton fabric. Use tightly woven cotton, such as quilting fabric or cotton sheets. T-shirt fabric will work in a pinch. Stack the two rectangles; you will sew the cloth face covering as if it was a single piece of fabric.



2. Fold over the long sides ¼ inch (0.64cm) and hem. Then fold the double layer of fabric over ½ inch (1.27cm) along the short sides and stitch down.



3. Run a 6-inch (15.24cm) length of 1/8-inch (0.32cm) wide elastic through the wider hem on each side of the cloth face covering. These will be the ear loops. Use a large needle or a bobby pin to thread it through. Tie the ends tight. Don't have elastic? Use hair ties or elastic head bands. If you only have string, you can make the ties longer and tie the cloth face covering behind your head.



4. Gently pull on the elastic so that the knots are tucked inside the hem. Gather the sides of the cloth face covering on the elastic and adjust so the mask fits your face. Then securely stitch the elastic in place to keep it from slipping.