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HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

HEALTH LAW VITALS

LIFE SCIENCES AND FDA COVID-19 UPDATE - MARCH 2020

FDA: SARS-CoV-2 (COVID-19) Is Not a Food Safety Threat

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As many Americans begin weeks of unwanted shut ins, the food industry is heading to work or working from home, with the goal of keeping a strong, safe, and abundant food supply. As recognized in guidance recently issued by the Department of Homeland Security, food producers and many of the businesses that support them are essential. Still, amidst the crisis, fears about the safety of food – and the ability of food and food packaging to transmit the novel coronavirus – have spread quickly. But the FDA has sought to reassure Americans that food is safe, providing a dedicated page for COVID-19 and stating that "[c]urrently there is no evidence of food or food packaging being associated with transmission of COVID-19." The FDA's remarks during a March 18th stakeholder briefing were similar.

The FDA continues to stress that COVID-19, at this time, is not known to be transmitted through food, and that a recall due to a sick worker would not be necessary, provided that good manufacturing practices are otherwise followed. The FDA advises that current good manufacturing practices and health hazard analyses mandated under the Food Safety Modernization Act are designed to address the challenges of preventing adulteration of food with pathogens. The FDA has also encouraged coordination with local and state officials, as protocols are likely to vary depending on the amount of community spread of COVID-19 in a particular geographic area, and has stated that questions such as whether a facility should be closed after a worker tests positive for COVID-19, and for how long, may vary and that food facilities need to work with state and local health departments, since the decisions are likely to be based on the risk of person-to-person transmission, rather than food safety.

Restaurants and retail establishments are finding their operations significantly curtailed by local and state orders intended to mitigate the risk of spreading

COVID-19. Many retailers and restaurants have moved quickly to close higher-risk operations, such as self-serve buffets, or condiment bars or salad bars. During last week's stakeholder call, FDA recommended that such offerings be temporarily closed. The FDA has also issued the following recommendations:

- Wash and sanitize food contact surfaces and utensils frequently;
- Food-service workers should practice frequent hand washing and glove changes before and after preparing food; and
- Frequently sanitize counters, cash registers and ordering stations, as well as condiment containers.

Some retailers have also opted to install temporary sneeze guards or similar shields in an effort to potentially reduce the risk to employees.

The FDA recommends using disinfectants outlined in the U.S. Environmental Protection Agency's list of disinfectants for use against SARS-CoV-2. As an extra precaution to help avoid the transmission of COVID-19 through surface contact, the FDA recommends frequent washing and sanitizing of all food contact surfaces and utensils.

The FDA is also closely monitoring the food supply chain and does not expect nationwide shortages of food, although the agency does advise that in some cases the inventory of certain foods at grocery stores might be temporarily low before stores can restock. The FDA stated that food production and manufacturing are widely dispersed throughout the United States and no widespread disruptions have been reported in the supply chain. However, it is clear to many that the food industry must strive to be creative and proactive to avoid shortages due to quickly fluctuating demand. For example, many foodservice distributors have found themselves left with too much product, while grocery retailers are scrambling to fill empty shelves. While grocery retailers are recruiting workers and raising hourly pay, the International Food Service Distributors Association predicts a $24 billion loss.[1] Reallocation may very well be the next order of the day.

[1] Source: https://www.foodsafetymagazine.com/news/foodservice-distributors-project-24-billion-loss-due-to-covid-19/, last accessed March 23, 2020.

FDA Issues Guidance for Conducting Clinical Trials During COVID-19

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On March 18, 2020, the FDA issued Guidance for Industry, investigators, and institutional review boards (IRBs) conducting clinical trials during the COVID-19 pandemic. The FDA recognized that certain challenges may arise in connection with COVID-19 that may create difficulty for clinical trials, such as quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected. Protocol modifications may be required, and there may be unavoidable protocol deviations. In its guidance, the FDA outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practices (GCPs), and minimizing risks to trial integrity. Noted considerations include, among others, the following:

- Since trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether

alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary, feasible, and sufficient to assure the safety of trial participants. Sponsors should determine if in-person visits are necessary to fully assure the safety of trial participants (e.g., to carry out procedures necessary to assess safety or the safe use of the investigational product appropriately). In making the decision to continue use or administration of the investigational product, the sponsor should consider whether the safety of trial participants can be assured with the implementation of the altered monitoring approach.

- In some cases, trial participants who no longer have access to the investigational product or site may need additional safety monitoring (e.g. withdrawal of an active investigational treatment).

- Changes in a protocol are typically not implemented before review and approval by the IRB, and in some cases, by FDA. Sponsors and clinical investigators are encouraged to engage with IRBs as early as possible when urgent or emergent changes to the protocol or informed consent are anticipated as a result of COVID-19. ***Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without IRB approval and before filing an amendment to the IND or IDE but be reported (and/or amendments must be submitted) afterwards.*** FDA encourages sponsors and investigators to work with their IRBs to prospectively define procedures to prioritize reporting of deviations that may impact the safety of trial participants.

- If scheduled visits at clinical sites will be significantly impacted, certain investigational products, such as those that are typically distributed for self-administration, may be amenable to alternative secure delivery methods. For other investigational products that are normally administered in a healthcare setting, consulting FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel) is recommended. In all cases, existing regulatory requirements for maintaining investigational product accountability remain and should be addressed and documented.

- With respect to efficacy assessments, FDA recommends consultation with the appropriate review division regarding protocol modifications to gather data in relation to efficacy endpoints, such as use of virtual assessments, delays in assessments, and alternative collection of research-specific specimens, if feasible. For individual instances where efficacy-endpoint data is not collected, the reasons for failing to obtain the efficacy assessment should be documented (e.g., identifying the specific limitation imposed by COVID-19 leading to the inability to perform the protocol-specified assessment).

- Sponsors, clinical investigators, and IRBs should consider establishing and implementing, or revising, policies and procedures to describe approaches that may be used to protect trial participants and manage study conduct during any COVID-19-related disruptions to the study. Changes to policies and procedures could address (among other things) changes relating to the informed consent process, study visits and procedures, data collection, study monitoring, adverse event reporting, and study personnel (e.g., investigators, site staff, and/or monitors), secondary to travel restrictions, quarantine measures, or the illness, itself. Policies and procedures should be compliant with applicable (regional or national) policies for the management and control of COVID-19. And, as mentioned above, depending upon the nature of the changes described above, a protocol (and/or IDE/IND) amendment may be required under the applicable regulations.

For all trials impacted by COVID-19, sponsors should include in the appropriate sections of the clinical study report (or in a separate study-specific document):

- Contingency measures implemented to manage study conduct during any disruption(s) to the study.
- A list of all study participants affected by the disruption, identifying such participants by their unique subject-number identifiers and by investigational site, along with a description of how the individual's participation was altered.
- Analyses and corresponding commentary addressing the impact of implemented contingency measures on the safety and efficacy results reported for the study.

FDA Demonstrates Regulatory Flexibility and Relaxes Policies on Hand Sanitizer Amid COVID-19

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The rapid spread of Coronavirus Disease 2019 (COVID-19) has sparked public fear and panic-induced stockpiling of alcohol-based sanitizing gels, leaving retailers and consumers without access to hand sanitizer. In response, the FDA has issued two new guidance documents on the preparation of certain alcohol-based hand sanitizer products by compounding pharmacies or by other manufacturing firms that register as over-the-counter (OTC) drug establishments to prepare alcohol-based hand sanitizers. In addition, the Alcohol and Tobacco Tax and Trade Bureau (TTB) has issued guidance that permits distilleries to produce hand sanitizer for the duration of the current emergency. These measures demonstrate the willingness of regulatory agencies to allow for flexible, practical approaches to meeting consumer and Industry needs.

In its recently issued guidance documents, which include the **FDA Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency** (issued March 14, 2020) ("***FDA Compounder Guidance***") and the **FDA Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19) Guidance for Industry** (issued March 19, 2020) ("***FDA Industry Guidance***"), the FDA has stated that it does not intend to take action against companies that prepare alcohol-based hand sanitizers for consumer use during this public health emergency in accordance with the applicable guidance. To be eligible for enforcement discretion under either FDA guidance *or* the TTB guidance, compounding pharmacies and other manufacturing firms, as well as distilleries, must utilize a specific formulation set forth in World Health Organization (WHO) guidelines, as described more fully in the guidance documents. Notably, FDA has communicated to us (via email on March 20, 2020) its then-current position that, in addition to the TTB guidance, distilleries should also follow the FDA Industry Guidance.

To summarize the FDA Industry Guidance, those wishing to produce hand sanitizer in response to the current emergency should adhere to the following requirements:

1. The hand sanitizer should be formulated using only the following United States Pharmacopoeia (USP) grade ingredients (percentage in final product formulation), consistent with WHO recommendations:

    a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and

Trade Bureau regulations in 27 CFR part 20; **or** Isopropyl Alcohol (75%, v/v) in an aqueous solution;

b. Glycerol (1.45% v/v);

c. Hydrogen peroxide (0.125% v/v); and

d. Sterile distilled water or boiled cold water.

The manufacturer acting solely under the guidance should not add other active or inactive ingredients due to FDA concerns that different or additional ingredients may impact the quality and potency of the product.

2. The manufacturer should ensure the ethanol or isopropyl alcohol active ingredient is correct and the correct amount of the active ingredient is used. A simple record should be used to document key steps and controls to assure each batch matches the formula developed for the drug product.

3. The hand sanitizer should be prepared under sanitary conditions and equipment utilized should be well maintained and fit for this purpose.

4. The manufacturer should use the most accurate method of analysis available at the site for verification of alcohol content in samples of the finished drug product before each batch is released for distribution. Methods can include gas chromatography (GC), alcoholmeter, hydrometer, or other chemical analysis of at least equivalent accuracy. The sample tested can be performed on in-process material before filling into the final containers to be distributed.

5. The hand sanitizer should be labeled consistent with the labeling attached to the FDA guidance.

6. New manufacturers that are not currently registered as OTC drug establishments will also have to register with the FDA and will receive automatic confirmation once the registration is complete. However, the registration can be completed contemporaneously and is not a bar to beginning production.

The FDA also advised that companies need to have a way to track adverse events for any products they manufacture and must submit adverse event reports to the FDA in accordance with applicable regulations.

FDA Scales Back Domestic Inspections Amid COVID-19 Pandemic

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The FDA announced that it has temporarily postponed all domestic routine surveillance facility inspections. These are facility inspections the FDA traditionally conducts every few years based on a risk analysis. Importantly, all domestic for-cause inspection assignments will be evaluated and will proceed on a case-by-case basis if deemed mission-critical. For example, food facilities experiencing a Class I recall may still reasonably expect an inspection. During this interim period, the FDA is evaluating additional ways to conduct for-cause inspections including, among other things, evaluating records in lieu of conducting an onsite inspection. Earlier in the month, the FDA postponed most foreign inspections through April 2020.

FDA Issues Temporary Guidance on Food Supplier Verification Audit Requirement

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To help prevent disruptions in the food supply-chain during the COVID-19 pandemic, the FDA issued a temporary policy for Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements. The policy states that the FDA will temporarily not enforce FSMA supplier verification onsite audit requirements if other appropriate supplier verification methods are used instead. Other supplier verification methods, such as sampling and testing or a review of food safety records, will be designed to provide sufficient assurance that hazards have been significantly minimized or prevented during the period of onsite audit delay. The following is a list of circumstances in which onsite audit requirements will not be enforced:

- A receiving facility or Food Supplier Verification Program ("FSVP") importer has determined that an onsite audit is the appropriate verification activity for an approved supplier, as reflected by its written food safety plan or foreign supplier verification program.
- The supplier that is due for an onsite audit is in a region or country covered by a government travel restriction or travel advisory related to COVID-19.
- In light of a government travel restriction or travel advisory, it is temporarily impracticable for the receiving facility or FSVP importer to conduct or obtain the onsite audit of the supplier (e.g., a receiving facility or FSVP importer is unable to obtain the services of a qualified auditor in the impacted country or region or travel to the foreign supplier to conduct the onsite audit).
- The receiving facility or FSVP importer temporarily selects an alternative verification activity or activities, such as sampling and testing food or reviewing relevant food safety records, and modifies its food safety plan or foreign supplier verification program to incorporate the alternative activity or activities. The alternative verification activity(ies) method is designed, in consideration of the temporary unavailability of supplier onsite audits, to provide sufficient assurance that the hazard requiring a supply-chain-applied control (or, for FSVP, the hazard that is being controlled by the foreign supplier) has been significantly minimized or prevented during the period of onsite audit delay.

The FDA will provide timely notice about the withdrawal of this policy, but asks facilities and FSVP importers to resume onsite audits within a reasonable period of time once it becomes practicable to do so. The FDA also instructs facilities and importers to update their food safety plans and foreign supplier verification programs accordingly.

FDA Revised Guidance on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic

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The FDA revised its guidance on postmarket adverse event reporting for medical products and dietary supplements during a pandemic to apply the guidance to the ongoing COVID-19 pandemic. The FDA acknowledges that companies, and the agency, itself, may be hit with workforce shortages during a pandemic at the same time that adverse event reporting for products deployed for the pandemic may increase. Accordingly, the FDA says the aim of

the guidance is to allow companies to "focus their limited resources" on submitting reports for products used against the pathogen causing the pandemic, as well as other specific reports identified in the guidance.

According to the Guidance, "normal adverse event reporting processes should be maintained to the maximum extent possible" during a pandemic, noting that companies should develop and implement a continuity of operations plan (COOP) to follow in the event of employee absenteeism. The FDA states that the guidance "is not intended to discourage adverse event reporting during a pandemic by firms that are able to continue reporting operations" and does not apply to reporting obligations for products authorized for emergency use or investigational products. The FDA says it does not intend to object to companies that are unable to submit adverse event reports to the agency within the required timeframes as a result of pandemic-related employee absenteeism, so long as they submit all delayed reports within six months of restoring their adverse event reporting processes "to their pre-pandemic state."

The FDA also advises companies to keep records of any adverse events that have been stored and document when their reporting processes are restored. FDA says there are some situations where it will expect companies to comply with normal reporting requirements during a pandemic, such as newly emerging product-related safety issues and product problems associated with adverse events.

FDA Issues "Immediately in Effect" Guidance to Accelerate Availability of COVID-19 Diagnostic

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The FDA issued immediately-in-effect guidance to accelerate the development of certain laboratory tests for the urgent need caused by SARS-CoV-2. The FDA provides recommendations, among others, for serological tests, puts forth a policy for states to take responsibility for tests, and announces enforcement discretion for commercial manufacturers using new commercially developed tests prior to the FDA granting an emergency use authorization, under certain circumstances.

- **Laboratories Certified Under CLIA That Meet the CLIA Regulatory Requirements May Perform High-Complexity Testing Using Their Validated Tests Prior to EUA Submission.** This policy applies to laboratories certified under CLIA to perform high-complexity testing to perform and that seek to develop and perform diagnostic tests to detect the SARS-CoV-2 virus and pursue EUA authorization from FDA for those tests. The FDA states that "for a reasonable period of time after validation and while they are preparing their EUA requests, FDA does not intend to object to the use of these SARS-CoV-2 tests for specimen testing." Accordingly, after validation and subject to certain conditions, EUA CLIA labs, can begin to offer their SARS-CoV-2 tests.
- **State Authorization of Laboratories Certified Under CLIA That Meet the CLIA Regulatory Requirements to Perform High-Complexity Testing.** The guidance allows a state to authorize laboratories within the state to offer COVID-19 diagnostic tests. The FDA notes it will "not be reviewing the process adopted by the State," and the FDA expects that such "states as part of their oversight process will require laboratories developing SARS-CoV-2 tests to validate those tests prior to use." The FDA also recommends that laboratories that develop and perform a test for COVID-19 under this policy to notify the FDA that they have started clinical testing.
- **Commercial Manufacturer Development and Distribution and Laboratory Development and Use of Serology Tests Without an EUA.** The

policy applies to developers of serology tests that identify antibodies (e.g., IgM, IgG) to SARS-CoV-2 from clinical specimens. This policy is limited to testing in laboratories or by healthcare workers at the point-of-care. This policy does not apply to at home testing. Because serological tests are less complex than molecular tests and are solely used to identify antibodies to the virus, the FDA does not intend to object to the development and distribution of serological tests by commercial manufacturers or development and use by laboratories of serology tests to identify antibodies to SARS-CoV-2 where the test has been validated, notification is provided to FDA, and information along the lines of the following is included in the test reports:

- This test has not been reviewed by the FDA.
- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
- Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E

These policies should increase the availability of COVID-19 diagnostic tests. See the Guidance for more information.

HHS Extends PREP Act Immunity to COVID-19 Countermeasures

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The U.S. Department of Health and Human Services issued a declaration (the "Declaration") under the Public Readiness and Emergency Preparedness Act (the "PREP Act") to protect "Covered Persons" from liability in relation to the manufacture, distribution, or administration of "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product" (or "Covered Countermeasures"). Covered Persons include manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as well as certain additional persons connected to the administration of the Covered Countermeasures.

To qualify for protection under the Declaration, Covered Countermeasures must also be "'qualified pandemic or epidemic products,' or 'security countermeasures,' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act." Examples of the types of liability covered under the Declaration include claims alleging negligence against a manufacturer in connection with the development of a vaccine, negligence claims against a healthcare provider for prescribing the wrong dose of a Covered Countermeasure, and claims

relating to the management and operation of a site where Covered Countermeasures are stored, shipped, transported, or offered for sale (e.g., a slip-and-fall injury or vehicle collision). The Declaration does not, however, provide immunity from liability arising from willful misconduct. The Declaration is retroactively effective as of February 4, 2020 and provides protection through October 1, 2025. See the Declaration for more information.

FDA Takes Action to Increase U.S. Supplies in Response to COVID-19

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The FDA took action to increase U.S. supplies to support the U.S. response to COVID-19 by providing instructions to manufacturers importing personal protective equipment and other devices. The FDA is engaging the import trade community during this pandemic to facilitate the entry of needed products, including PPE, into the U.S. The FDA provided the below instructions to importers to clarify the types of PPE that can be imported without engaging with FDA:

1. **Non-FDA-regulated general purpose personal protective equipment (masks, respirators, gloves, etc.).** Personal protective equipment for general purpose or industrial use (that is, products that are not intended for use to prevent disease or illness) are not regulated by the FDA and entry information should not be transmitted to FDA. At the time of entry for these products, importers should transmit entry information to US Customs and Border Protection using an appropriate HTS code with no FD Flag or using an appropriate HTS code with an FD1 flag and a 'disclaim' for FDA.
2. **Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA).** Entry information should be submitted to the FDA, however reduced FDA information is required for review. At the time of entry, importers should transmit an Intended Use Code of 940.000: Compassionate Use/Emergency Use, and an appropriate FDA product code. A list of products and the appropriate product codes that are currently authorized by an EUA, include: Diagnostic tests – QPK, OTG, QKO, QJR and Masks/Respirators – NZJ.
3. **Products regulated by FDA as a device, not authorized by an EUA, but where an enforcement discretion policy has been published in guidance.** When importing such devices, entry information should be submitted to FDA. At the time of entry, importers should transmit an Intended Use Code of 081.006: Enforcement discretion per final guidance, and an appropriate FDA product code.

For further information regarding entry submission requirements, see the FDA Supplemental Guidance for ACE.

FDA Warns Consumers About Unauthorized Fraudulent COVID-19 Products

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The FDA issued a Consumer Update advising consumers to be beware of fraudulent coronavirus tests, vaccines and treatments. The FDA has seen

unauthorized fraudulent test kits for COVID-19 being sold online. Currently, the FDA has not authorized any test that is available to purchase for testing yourself at home for COVID-19. The FDA is concerned that deceptive and misleading products might cause Americans to unknowingly spread COVID-19 or not get treated appropriately if they use an unauthorized test or to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. The FDA warns that the products likely do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications. The FDA made clear that **there are no FDA-approved products to prevent COVID-19**. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. The agency warns against taking any form of chloroquine unless it has been prescribed by a health care provider and obtained from legitimate sources.

Here are some tips to identify false or misleading claims:

- Be suspicious of products that claim to treat a wide range of diseases.
- Personal testimonials are no substitute for scientific evidence.
- Few diseases or conditions can be treated quickly, so be suspicious of any therapy claimed as a "quick fix."
- If it seems too good to be true, it probably is.
- "Miracle cures," which claim scientific breakthroughs or contain secret ingredients, are likely a hoax.
- Know that you can't test yourself for coronavirus disease.

The FDA has been working with retailers to remove dozens of misleading products from store shelves and online and will continue to monitor social media and online marketplaces promoting and selling fraudulent COVID-19 products.

FDA announces process for FDA guidance documents related to COVID-19

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The FDA has announced procedures, which operate within the FDA's established good guidance practices regulations, for making available FDA guidance documents related to COVID-19. The FDA believes that these procedures will allow the FDA to rapidly disseminate its recommendations and policies related to COVID-19. The Guidance documents, will be implemented without prior comment and will be accessible on the internet from the FDA web page entitled "Coronavirus Disease 2019 (COVID-19)."

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